

# ANNUAL REPORT 2003



# COMPANY PROFILE

PhotoCure ASA - Annual Report 2003

## Table of Contents

Milestones	1
President's Statement	2
The PhotoCure Share	4
Corporate Governance	6
Board of Directors	8
Executive Officers	9
Metvix®	10
Hexvix®	13
Benzvix®	15
PCI Biotech AS	16
Research and Development	17
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Directors' Report	18
Income Statement	21
Balance Sheet	22
Cash Flow Statement	24
Notes to Financial Statements	25

An Annual Report in Norwegian, including only Directors' Report and Financial Statements, is available on [www.photocure.com](http://www.photocure.com) or can be obtained by contacting PhotoCure ASA.

Metvix, Hexvix, Benzvix, Aktillite, Curelight and PhotoCure are trademarks of Photocure ASA.



**P**hotoCure ASA is a Norwegian pharmaceutical company founded in 1993. The company's mission is to develop and sell pharmaceuticals and medical devices targeting key dermatology and oncology markets, using its proprietary technologies.

The company's lead product, Metvix®, is developed for the treatment of actinic keratosis (pre-cancerous skin lesions) and basal cell carcinoma (skin cancer). It is approved in 16 European countries, in addition to Australia and New Zealand. Metvix is being marketed by PhotoCure in the Nordic countries and is licensed exclusively to Galderma S.A. for marketing and sales in rest of the world. The product was launched in Germany and UK in 2003. Furthermore pre-launch activities have commenced in a number of countries. In addition, PhotoCure's New Drug Application (NDA) for Metvix as a treatment for actinic keratosis has been deemed "approvable" by the US Food and Drug Administration (FDA) and the company expects to receive final approval for the use of Metvix for this indication during first half of 2004.

PhotoCure has also filed the first Marketing Authorisation Application for its second product, Hexvix®, for the European Union, with Sweden as the reference member state. A positive preliminary assessment of this application has been received from the Swedish Medical Products Agency (MPA) and a final approval from the Swedish authorities is expected during the 2004.

A Swedish approval will pave the way for EU submission through the Mutual Recognition Procedure. PhotoCure is also developing Benzvix® for diagnosis and treatment of early-stage cancers of the gastro-intestinal tract, particularly oesophageal and colon cancers. Several pilot clinical studies using Benzvix are ongoing.

PhotoCure has its headquarter in Oslo, Norway and has 40 employees. The company operates as a virtual company, outsourcing production, most of its R&D activities as well as other functions.

## Metvix®

- Revenues increased to NOK 55.1 million in 2003 (NOK 25.2 million in 2002)
- Galderma initiated launch of Metvix and Aktelite® in Germany and UK in 2003, with several countries to follow
- Approval obtained in Australia, Switzerland, and Malta. Metvix is previously approved in 14 European countries and New Zealand
- Marketing authorisation for Metvix is pending in US, Czech Republic, Hungary, Slovenia, South Africa, Mexico and Brasil.
- A total of 171 centres now established in the Nordic countries

## Hexvix®

- Positive preliminary assessment of Marketing Authorisation Application filed in Sweden in December 2002
- Positive results from first US phase III clinical trial
- Positive results from second European phase III clinical trial
- Collaboration agreement signed between PhotoCure and Karl Storz, a leading cystoscopy provider

## Benzvix®

- Development as a product for photo-diagnosis and treatment for early lesions in the gastrointestinal tract progressing
- New pilot clinical studies initiated

## PCI Biotech AS

- Improved delivery in living cells demonstrated for some forms of oligonucleotides, a promising class of macromolecules
- Proof-of-principles obtained in animals for treatment of bone cancer (osteosarcoma)



# PRESIDENT'S STATEMENT

PhotoCure ASA - Annual Report 2003



In 2003, PhotoCure continued to make progress in securing the commercial success of its first product, Metvix® for treatment of pre-cancerous and cancerous skin disorders. In the Nordic region, sales doubled in 2003 compared with 2002. Metvix also achieved its first commercial sales in England and Germany following launches managed by PhotoCure's global marketing partner, Galderma S.A. During 2003, Metvix gained further marketing approvals in Australia, Switzerland and Malta, and is now approved for marketing in 16 European countries as well as Australia and New Zealand.

Hexvix®, PhotoCure's second pharmaceutical product for the detection of bladder cancer, expects marketing approval from the Swedish Medical Products Agency during 2004. The clinical results are excellent and we believe that this product will become a commercial success.

In 2003, total operating revenues more than doubled compared to 2002. In addition, costs are reduced as R&D investments in Metvix and Hexvix decreased in 2003 compared to 2002. This significant progress resulted in a substantial reduction in net loss from NOK 96.0 million in 2002 to NOK 42.8 million in 2003.

## Metvix: Increasing Sales

PhotoCure has worked hard in establishing the Metvix treatment in the Nordic region. Sales more than doubled in this area in 2003 and contributed to the significant increase in total revenues. PhotoCure continues to establish and support clinical centres in Nordic markets, which offer Metvix treatment.

Metvix commercialisation took a major step forward in 2003, with its first official sales in Germany and the UK – territories covered by Galderma. Clinical acceptance has been encouraging and substantial sales growth is anticipated in 2004. Metvix is scheduled for launch in Italy, Spain, Belgium, Switzerland and Australia in 2004. Galderma has also started pre-launch activities in a number of other countries.

## Metvix: Increasing Market Penetration

The number of countries in which Metvix has gained marketing approval continues to grow. In 2003, Metvix secured marketing approval both in Switzerland and Australia for the treatment of skin cancer (basal cell carcinoma) and premalignant skin changes (actinic keratosis). With the world's highest incidence of sun-induced skin diseases, Australia is a particularly important market. Actinic keratosis, is common in adults over 40 years of age. If this condition is not properly treated, it can develop into a skin cancer with the ability to metastasise (squamous cell carcinoma).

The incidence of basal cell carcinoma is also high in Australia with 200,000 new cases reported each year. Since lesions occur on sun-exposed areas such as the face, scalp,

neck and hands, there is a real need for non-disfiguring, non-invasive treatments with high cure rates and excellent cosmetic outcomes, such as Metvix. World wide, there are an estimated 2 million new cases of basal cell carcinoma each year and the corresponding figure for actinic keratosis is 20 million cases.

Marketing authorisation applications for Metvix have been filed in the US, Czech Republic, Hungary, Slovenia, South Africa, Brazil and Mexico. In 2004, Galderma intends to file applications in countries joining the EU and Argentina.

In the US, PhotoCure expects to receive final approval for a New Drug Application for Metvix in the treatment of actinic keratosis from the America Food and Drug Administration (FDA) during the first half of 2004. PhotoCure has also applied for a basal cell carcinoma indication for Metvix in the US. In September, an advisory committee to the FDA, the Dermatologic and Ophthalmic Drugs Advisory Committee, did not recommend Metvix to be approved for first line treatment of primary nodular basal cell carcinoma. However, the Committee unanimously agreed that there are no safety concerns related to the Metvix treatment, and stated that there is a medical need for Metvix in certain patient populations. PhotoCure is working with the FDA with the aim of obtaining approval for a basal cell carcinoma indication.

## Metvix: New Indications

Ongoing clinical trials suggest that Metvix may have a wider commercial scope. In addition to basal cell carcinoma and actinic keratosis, results indicate that Metvix has promise for the treatment of early squamous cell carcinoma.

Metvix, in the treatment of this more dangerous form of non-melanoma skin cancer, provides better response rates and cosmetic outcomes compared with current treatments tested. Metvix may also be useful in the prevention and treatment of skin lesions in immunosuppressed organ transplant patients. Non-melanoma skin cancers are 50-100 times more frequent and more aggressive in this group of patients. Explorative studies on sebaceous gland disease (acne) are promising and will be followed by formal studies for regulatory approval.

### **Hexvix: Close to Market**

PhotoCure's second product, Hexvix, for improved detection of bladder cancer, is about to enter the market. Marketing approval from the Swedish Medical Products Agency is expected during the 2004. This will facilitate European submissions through the EU's Mutual Recognition Procedure. PhotoCure is now focussing on pre-launch activities to maximise the commercial impact of Hexvix, as well as continuing to evaluate possible partners for sales and marketing activities outside the Nordic region. In the US, a clinical phase III programme is ongoing as part of preparations for a US application.

When instilled in the bladder, Hexvix concentrates in cancer cells to aid identification and guidance in the treatment of cancerous lesions. Current diagnostic methods may miss a significant number of early stage bladder tumours, which can lead to recurrence after initial therapy. Because Hexvix fluorescence cystoscopy is easy to carry out, and has a good safety profile, it can easily be added to standard diagnostic procedures to improve

detection. The market for this application is large, with more than four million cystoscopic tests being carried out annually in Europe and the US alone. Earlier and more accurate detection of bladder cancer promises better patient management and more effective treatment.

Hexvix Imaging can also be used in fluorescence-guided surgery. Furthermore, PhotoCure expects Hexvix to be used in the treatment of bladder cancer, as the photosensitive molecules in Hexvix can be activated to destroy cancer cells using an appropriate light source. A pilot study is underway to assess the effectiveness of Hexvix in the treatment of bladder cancer and the preliminary results are promising.

During the year, PhotoCure signed a collaboration agreement with Karl Storz, to develop Hexvix and the Karl Storz D-light system for the diagnosis of bladder cancer. The objective is to obtain marketing authorisation for both products in the US.

### **Product Pipeline**

PhotoCure continues to invest in its product pipeline. Pilot clinical studies involving photodynamic therapy diagnosis of early stage gastro-intestinal tract and gynecology cancers, have been encouraging. Further preliminary clinical studies will be undertaken in 2004 with the aim of moving into formal clinical trials.

Through its subsidiary, PCI Biotech AS, PhotoCure continues to develop new technologies for drug delivery. PhotoCure is also strengthening its anticancer portfolio through its investment in Algeta ASA (formerly Anticancer

Therapeutic Inventions). The company's first product Alpharadin™, which targets bone metastases from prostate cancer (and breast cancer), is now in phase II clinical trials.

### **Future Prospects**

In 2004, PhotoCure expects to see further progress in the Metvix commercialisation as it continues to focus efforts on securing the success of this first product. PhotoCure will concentrate on establishing new clinics in the Nordic area, as well as providing continued support to existing clinics. Extended use in acne and in immunosuppressed organ transplant patients increases the market potential. We will also continue work to raise general awareness of Metvix among health professionals and patients. Galderma's extensive marketing efforts outside the Nordic regions promise greater market penetration and increased sales in 2004.

Approval of Hexvix in Sweden will open the door to European markets, allowing PhotoCure to focus on implementing pre-market activities in a number of countries. PhotoCure expects Hexvix to achieve substantial revenues.

The chance of entering into formal clinical trials with a third pharmaceutical product is increased due to the very promising clinical pilot data in gynecology and gastro-enterology.

**Vidar Hansson**

*President and CEO of PhotoCure*

# THE PHOTOCURE SHARE



**In 2003, PhotoCure's share price ended the year up 50% at NOK 54.00. The Oslo Stock Exchange Benchmark Index increased with 48% in the same period.**

## PhotoCure ASA - Annual Report 2003

### Listing

PhotoCure ASA is a public limited company with headquarters in Oslo, Norway. The company's shares were listed on the main list of the Oslo Stock Exchange in 2000. The ticker symbol is PHO (Reuters PHO.OL).

### Performance Over the Year 2003

The PhotoCure share have recovered significantly during 2003 compared to 2002, rising from NOK 36 at the end of 2002 to NOK 54 by the end of 2003, a increase of 50%. During 2003, the PhotoCure share has gained increased confidence from the market due to Metvix® sales and growing confidence in the revenue potential for Hexvix®. This positive trend has nevertheless been partly offset by the non-expected recommendation from the FDA Advisory Committee not to recommend Metvix for approval for the treatment of primary nodular basal bell carcinoma.

### Trading Volume

During the course of 2003, the average daily trading volume of PhotoCure's shares reported on or to the Oslo Stock Exchange was 44,384 shares. One round lot consists of 100 shares. A total of 11.1 million shares were traded on the Oslo Stock Exchange in 2003.

### Market Capitalisation

PhotoCure's market capitalisation at the end of 2003 was NOK 949 million (NOK 628 million in 2002). By 20 February 2004 it had increased to NOK 1,305 million.

### Shares and Share Options

At the end of 2003, the outstanding number of shares was 17,577,000 shares. PhotoCure had also issued 212,327 share options

and warrants at the end of 2003. Of these, 162,327 options were held by employees of the company.

### Financial Events 2004

PhotoCure intends to release its quarterly financial statements during 2004 on the following dates:

7 May 2004	Report 1st Quarter 2004
20 August 2004	Report 2nd Quarter 2004
20 October 2004	Report 3rd Quarter 2004

The company's Annual General Meeting will be held in Oslo on the 15 April 2004.

### Shareholder Information

Share price sensitive information is distributed through stock exchange notices, press releases, reports and presentations. This information is available on Oslo Stock Exchange's website [www.ose.no](http://www.ose.no) and/or our website [www.photocure.com](http://www.photocure.com). On our website there is also other useful information about PhotoCure and its products as well as coverage by financial analysts.

### Share Ownership

PhotoCure had 2,565 shareholders as of 31 December 2003. Domestic shareholders in Norway hold 87% of the shares.

### PhotoCure Share price up to 20 February 2004 (NOK/ share)



### Top Ten Shareholders as of 31 December 2003

Shareholder	Number of Shares	% of issued share capital
Radiumhospitalets Forskningsstiftelse	3,759,000	21.39%
Gezina AS	960,373	5.46%
Sundt AS	420,749	2.39%
Ferd AS Invest	400,000	2.28%
Vidar Hansson/Varak AS	373,500	2.12%
Brown Brothers Harriman & Co	353,200	2.01%
Sig. Bergesen D.Y. almennyttige stiftelse	352,750	2.01%
Marlin Verdi AS	345,000	1.96%
Morgan Stanley and Co. Ltd.	325,280	1.85%
Vicama AS	285,221	1.62%

### Shareholders According to Size of Shareholding at 31 December 2003

Shareholdings	Number of Shareholders	Number of Ordinary Shares	Percentage of Ordinary Shares
1-999	1,552	447,498	2.5%
1,000-9,999	816	1,960,382	11.1%
10,000-99,999	169	4,564,509	26.0%
100,000-499,999	26	5,885,238	33.5%
500,000 and more	2	4,719,373	26.9%
<b>Total</b>	<b>2,565</b>	<b>17,577,000</b>	<b>100.0%</b>





# CORPORATE GOVERNANCE

PhotoCure ASA - Annual Report 2003



**PhotoCure's main goal is to create value for its shareholders. Well-defined corporate bodies and prudent management are important factors in achieving this goal. In this section, important parts of PhotoCure's corporate governance are described.**

## Shareholder Rights

PhotoCure treats all shareholders equally, by having only a single share class, no voting restrictions and no restrictions on trading.

## General Meeting

The Annual General Meeting (AGM) of the company is held each year before 1st of July. The AGM decides on:

- Approval of the Profit & Loss Account and Balance Sheet
- Employment of net income or coverage of net loss based on the finalised balance sheet and payment of dividends.
- Election of the Board of Directors and decision on remuneration to the board members.
- Appointment of auditor and decision on her/his remuneration.
- The AGM shall also address and decide on cases listed in the summons and other matters required by law.

Voting on resolutions at the AGM can be done by personal presence or by power of attorney. Owners of shares, which are registered in the name of a nominee, are not entitled to vote under Norwegian law, nor are the persons who are designated in the register as nominees. If these shareholders wish to vote or

be present at the AGM, the shareholder must request that the nominee transfer the shares to a Norwegian securities account registered in the shareholder's name prior to the shareholder's meeting.

Apart from the AGM, extraordinary general meetings of shareholders may be held whenever considered necessary by the Board of Directors. An extraordinary general meeting shall also be convened for the consideration of specific matters at the written request of our auditor or of shareholders representing at least 5% of our share capital.

For mandates granted to the Board of Directors, see Notes to the financial statements, Note 15.

## Board of Directors

The Board of Directors of the Company shall consist of up to seven members and appoints a chairman and a deputy chairman among its elected members. All members are independent of management and free from any business or other relationship which could materially interfere with the exercise of independent judgement. Profiles on each are included on page 8. The Board of Directors had 9 meetings in 2003.





The Board of Directors can grant power of attorney. The authorised signatory of the Company is exercised by the chairman of the Board of Directors and the deputy chairman together, or three board members together.

The Board is responsible for the strategy, performance, control and management of the company. The responsibility for implementing the Board's courses of action is delegated to the Chief Executive within certain limits authorised by the Board.

## Remuneration and Performance Evaluation of Senior Management

The Company has a Remuneration committee consisting of the Chairman and the Deputy Chairman of the Board of Directors. The Company operates an incentive programme for management, which is outlined in the Notes to Financial Statements, Note 2.

Total compensation, bonuses, and number of shares and share options owned or granted directly or indirectly by members of the Board of Directors and Chief Executive Officer are detailed in the Notes to Financial Statements, Note 2 and 15. Number of shares and share options owned by senior management and related parties are also detailed in these notes.

## External Communications

Share price sensitive information is distributed through stock exchange notices, press releases, reports and presentations. This information is available on Oslo Stock Exchange's website [www.ose.no](http://www.ose.no) and/or our website [www.photocure.com](http://www.photocure.com). On our website there is also other useful information about PhotoCure and its products as well as coverage by financial analysts.

The Articles of Association of PhotoCure ASA are in Norwegian. The following is merely a translation of the actual Articles of Association.

## Articles of Association for PhotoCure ASA

As of 19 August 2003

### § 1

The Company's name is PhotoCure ASA. The Company is a public limited company.

### § 2

The Company's headquarters is located in Oslo, Norway.

### § 3

The purpose and main business of the Company is to operate in photodynamic therapy and related areas, and anything thereby connected.

### § 4

The share capital of the company amounts to NOK 8,788,500 divided on 17,577,000 shares at NOK 0.50 each, registered by name and fully paid in. All shares in the Company shall be registered with the Norwegian Registry of Securities (VPS).

### § 5

The Board of Directors of the Company shall consist of up to 7 members. The Board of Directors appoints a chairman and a deputy chairman among its elected members.

The Board of Directors can grant power of attorney. The authorised signatory of the Company is exercised by the chairman of the Board of Directors and the deputy chairman together, or three board members together.

### § 6

The Annual General Meeting is held each year before 1st of July.

The General Meeting decides on:

1. Approval of Profit and Loss Account and Balance Sheet.
2. Employment of net income or coverage of net loss based on the finalised balance sheet and payment of dividends.
3. Election of the Board of Directors and decision on remuneration to the board members.
4. Appointment of auditor and decision on her/his remuneration.
5. The General Meeting shall also address and decide on cases listed in the summons and other matters required by law and directions.

### § 7

Extraordinary general meetings are held when the Board of Directors finds it necessary, or when it is required by the Company's auditor or shareholders representing a minimum of 1/10 of the share capital, and when information on matters to be treated is enclosed. The share capital, when it at the same time is enclosed information on matters to be treated.

### § 8

All current laws and regulations pertinent to public limited companies apply to PhotoCure at all times.

## BOARD OF DIRECTORS

PhotoCure ASA - Annual Report 2003



**Erik Engebretsen**, age 55, was elected as a Director of PhotoCure in March 2001 and Chairman of the Board in March 2002. Mr Engebretsen is a graduate of the Norwegian School of Management and holds an MBA and MS from the University of Wisconsin-Madison. He is the Managing Director of Gezina AS, a private venture and investment company. Previously he has served as Chief Executive Officer and Chief Financial Officer in various public companies. He is also a member of the Board of Directors with a number of public and private companies.



**Per-Olof Mårtensson**, age 66, was elected as a Director of PhotoCure in 1996 and Deputy Chairman of the Board in 1998. He is currently Chairman of the Board of Karo Bio after being President and Chief Executive Officer of the same company. Before joining Karo Bio, he held various senior management positions in the pharmaceutical industry, including Executive Vice President of Pharmacia AB, President of AB Leo, Vice President of Pharmaceutical Operations of Astra AB and Member of the Advisory Board of HealthCap AB, a Swedish investment fund in the medical field. He is also a member of the Board of Directors of a number of public and private companies, including Maxim Pharmaceuticals Inc. and BioInvent International AB.



**Halvor Kr. Bjerke**, age 57, was elected as Director of PhotoCure in October 1996 and served as Chairman of the Board from April 1998 to March 2002. Mr. Bjerke is a practising lawyer. He was Vice President and Company Secretary of Saga Petroleum ASA for 12 years (ending 1999), after having served in the same position in GECO for 3 years (ending 1987). Earlier, he was employed by the Norwegian Ministry of Finance and the Norwegian Inland Revenue. Mr. Bjerke served as Chairman of the Board of the Norwegian Radium Hospital Research Foundation from 1996 to 2002 and is currently Chairman of the Board of MedProbe AS (since 1987-), and Chairman of the Commission of Appeal for the Norwegian R & D Tax Refund (SkatteFunn) (since 2001-).



**Lars Lindegren**, age 66, was elected as a Director of PhotoCure in March 2000. He is currently Chairman of the Board of Metcon Medicin AB and serves on the Board of Wilhelm Sonesson AB, Angiogenetics Sweden AB and Gallileo Genomics Inc. He has held various senior management positions in the pharmaceutical industry including Executive Vice President of Pharmacia AB and President of Astra Pharmaceuticals International.



**Birgit Agneta Stattin Norinder**, age 55, was elected as a Director of PhotoCure in April 2003. Mrs. Norinder is a trained pharmacist and she has held senior management positions in various international pharmaceutical companies, including Pharmacia & Upjohn, Glaxo Group Research, Astra, Pfizer and Parke-Davis. She has also served as CEO of Prolifix Ltd., a biotech company with a focus on oncology. In addition, she serves on the boards of Antisoma Plc, InDex Pharmaceuticals AB, Probi AB and the Foundation of Strategic Research.

## EXECUTIVE OFFICERS

**Vidar Hansson**, M.D., Ph.D., age 60, has served as the President and Chief Executive Officer since January 1997. Before joining PhotoCure as CEO, Dr Hansson was Chairman of the Board of Directors of the Norwegian Radium Hospital Research Foundation and coordinator of the Norwegian Radium Hospital's priority programmes in research for new diagnostics and therapies as well as Professor in Medical Biochemistry at the University of Oslo since 1981. Dr Hansson holds a Ph.D. in Molecular Endocrinology/Molecular Biology.



**Kjetil Hestdal**, M.D., Ph.D., age 44, has served as the Vice President of Research and Development since January 1997. Before joining PhotoCure, Dr Hestdal served as the Project Manager/Medical Expert at Sandoz (now Novartis) and as Senior Scientist at Rikshospitalet. Dr Hestdal holds a Ph.D. in Immunology.



**Geir Christian Melen**, age 40, has served as the Chief Financial Officer since February 1997. Mr Melen has a Master of Science degree in business from the Norwegian School of Business and Administration and, before joining PhotoCure, he served from 1990 to 1997 as Strategy and Economic Planning Manager and Finance Manager of Saga Petroleum ASA, now part of Norsk Hydro ASA. He previously served as a business consultant for Deloitte Haskins and Sells Management Consultants AS.



**Hilde Morris**, DVM, age 46, has served as Vice President Strategic Marketing since August 2003. Dr. Morris was employed in Schering Norge as Medical Director in 1986. From 1990 to 1999 she worked as Clinical Project Director in Nycomed Imaging, after which she joined PhotoCure as Clinical Project Director. Dr. Morris has a degree in veterinary medicine and she attended the Program for Management Development at Harvard Business School in 2002.





**Metvix offers an efficient treatment for actinic keratosis (pre-cancerous skin lesions) and basal cell carcinoma (skin cancer) with a superior cosmetic outcome. Metvix sales are progressing in the Nordic countries, and the investments that have been made in sales and marketing are starting to generate significant revenues. Galderma, PhotoCure's partner for sales and marketing outside the Nordic region, has recently started to launch the product in Germany, UK and New Zealand. In 2004, Galderma will initiate launch of Metvix in five new markets.**

## Metvix Sales in Progress

As Metvix was approved in all the Nordic countries in 2002, PhotoCure has been able to focus fully on sales and marketing activities in 2003.

The marketing of Metvix in the Nordic countries has resulted in favourable conditions for future sales growth, as the acceptance of Metvix among dermatologists is high. Of a total of 400 dermatology clinics in the Nordic region, approximately 171 clinics offer the Metvix treatment today. The majority of these clinics are situated in Sweden and Norway. In Denmark and Finland, PhotoCure is mainly focussing on the establishment of new clinics, while the activities in Norway and Sweden are mainly concentrated on follow-up of already existing Metvix clinics, including training of health personnel.

Drug reimbursement is established in Sweden, Norway, Finland, and partly in Denmark, where the Metvix cream is reimbursed on a regional level. In addition, reimbursement of the Metvix treatment procedure for dermatologists with a private practice is now in place in Norway and in certain regions in Denmark.

Market analyses performed in 2002 show that the occurrence of actinic keratosis and basal cell carcinoma is higher than what is officially reported to the authorities. It is estimated that there are approximately 45,000 new cases of basal cell carcinoma each year in the Nordic countries, while the figure for actinic keratosis is estimated to be ten times higher. The number of treatments of basal cell carcinoma in the Nordic countries is estimated to approximately 80,000 yearly, while the number

of treatments of actinic keratosis is around 110,000. The market analyses also show that close to 100% of all dermatologists in the Nordic countries are familiar with Metvix and that they are positive to the method, which is considered an important supplement to the treatment of actinic keratosis and basal cell carcinoma.

## Taking Metvix Worldwide

In the course of 2003, Galderma S.A., PhotoCure's partner for marketing and sales of Metvix in the markets outside the Nordic region, has carried out the first Metvix launches in its market areas. Galderma launched Metvix on the German market in February, and this was marked with a successful launch symposium in Berlin, where 150 opinion leaders within dermatology participated. To follow up the launch in Germany, Galderma has provided training of health personnel, distributed and installed lamps at clinics and assisted the clinics in their first Metvix treatments. Galderma's second launch was in May, when Metvix was introduced on the UK market. On this occasion, a launch symposium for selected UK opinion leaders was held at the World Congress for Cancers of the Skin in Seville. Galderma has established several educational centres in the UK, to ensure adequate training for dermatologists who wish to start with the Metvix treatment. Galderma is pleased with the clinical acceptance that Metvix has received in Germany and the UK and the initial sales of the product.

## About Galderma S.A.

Galderma S.A., a joint venture between Nestlé and L'Oréal, is the only global company exclusively dedicated to providing dermatological

treatments. The company has subsidiaries in 32 countries, with sales force operations in more than 70, visiting approximately 85% of the estimated 65,000 dermatologists around the world.

Galderma has a centralised Corporate Marketing structure that coordinates and implements worldwide product strategies and core marketing campaigns for Global Strategic Brands such as Metvix. This structure can then provide support to experienced local marketing teams that carry out plans and adapt strategies to suit their local markets. Specialised sales forces are being employed prior to launch in each market.

In addition to unrivalled market coverage, Galderma has close relationships with major opinion leaders and has extensive knowledge of the indications for which Metvix is likely to be developed in the future. The company therefore represents an excellent choice to take Metvix to a worldwide dermatology market.

### Actinic Keratosis

Actinic keratoses are very common, pre-cancerous lesions that arise on photo-damaged skin, with extensive sun exposure and skin type being the most important factors in their development. Approximately 60% of squamous cell carcinoma develop from an actinic keratosis. Thus, the lesions require careful evaluation and effective treatment. Despite this, PhotoCure estimates that in Europe, only 20-30% of the five million estimated cases are treated. The incidence is also particularly high in Australia, with approximately two million new cases per year, and the US, with an estimated ten million cases annually. Therefore,

actinic keratosis represents a significant and increasing market.

### Basal Cell Carcinoma

Basal cell carcinoma is the most common form of skin cancer, affecting an estimated one million US citizens each year. As with actinic keratosis, this condition is increasingly common owing to excessive exposure of skin to sunlight and an ageing population. The European Union also has a high annual incidence (exceeding 500,000) and in Australia, approximately 200,000 new cases are reported each year. The incidence of basal cell carcinoma is predicted to increase by 3-5% per annum.

### New Indications

PhotoCure has conducted a successful phase III clinical trial for the treatment of squamous cell carcinoma in situ, also called Bowen's disease. The study showed that Metvix is an effective and well-tolerated treatment option for patients with Bowen's disease. Metvix also has potential for use in the treatment of skin dysplasia in immuno-compromised patients, skin rejuvenation, wound healing, acne and warts.

### The Benefits of the Metvix Treatment

The Metvix treatment, which combines application of the Metvix cream and illumination with PhotoCure's light source Aktillite, has a number of key advantages:

- It is highly effective at killing cancer cells selectively, with little or no destruction of normal tissue
- It produces an excellent cosmetic outcome
- The procedure is straightforward and can be repeated if necessary
- Topical treatment means low risk of side effects



*Crusts and scales are removed ...*



*... Metvix is applied to the lesion ...*



*.. the cream is covered with plastic film and left to work for three hours ..*



*... the area is then illuminated with Aktillite for about ten minutes, and the cancerous cells die.*

## Aktilite®

PhotoCure has developed three different proprietary red light sources to be used in combination with the Metvix cream. The key characteristic of red light is its ability to penetrate human tissue, thus improving the ability of the Metvix treatment to permeate thicker lesions. The original broadband lamp CureLight 01 is still available together with PhotoCure's two more recently developed Aktilite lamps. Both Aktilite light sources are based on the durable technology using light emitting diodes (LEDs), thus making the lamps almost maintenance-free. Aktilite CL16 has 16 LEDs, irradiating an area of 4x5 cm, and the larger Aktilite CL128 has 128 LEDs, irradiating an area of 8x18 cm.

## Clinical Development of Metvix

Importantly, Metvix has consistently been the patient's preferred choice of treatment throughout trials. This is most likely attributable to the cosmetic benefits and the patient-friendly and non-invasive technique involved. During clinical trials, Metvix was used on more than 3,000 patients in over 100 clinical centres worldwide, encompassing Europe, Australia and the US.

A multi-centre phase III clinical trial in Australia yielded very positive results using Metvix for the treatment of difficult to treat basal cell carcinoma, with 89% of lesions cured after three months and 65% of cosmetic results rated excellent or good. In addition, two European multi-centre phase III studies demonstrated that the Metvix treatment gave initial results comparable to surgery in the treatment of nodular basal cell carcinoma and to cryotherapy in the treatment of superficial basal

cell carcinoma.

In the US, phase III clinical trials demonstrated that Metvix completely removed 88% of the actinic keratosis lesions tested and was judged cosmetically excellent by investigators for 91% of the patients involved.

Following favourable results from phase III trials in Europe, Australia and the US, Metvix had received regulatory marketing authorisation in 16 European countries, New Zealand and Australia by the end of 2003. Marketing authorisation applications for Metvix are pending in the US, the Czech republic, Hungary, Slovenia, South Africa, Brazil and Mexico. Further applications are scheduled for filing in 2004, including new countries joining the EU, Portugal, Netherlands and Argentina. PhotoCure's first New Drug Application for Metvix in the US for the treatment of actinic keratosis was deemed approvable in 2002 by the US Food and Drug Administration (FDA) and PhotoCure is confident of receiving a final approval for this indication during first half of 2004.

In February 2003, after completing two trials in nodular basal cell carcinoma, the company filed a second New Drug Application for Metvix in the US for the treatment of skin cancer (primary nodular basal cell carcinoma). The FDA reviewed the application in December and asked for additional data on Metvix in the treatment of primary nodular basal cell carcinoma. PhotoCure has initiated a discussion with the FDA for the possibility to obtain approval without commencing new studies.



Modular basal cell carcinoma. Complete response 3 months after Metvix treatment.

METVIX STATUS	
Milestones	Countries Completed
Approvals 2001	Austria, Belgium, Denmark, Finland, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Norway, Spain, Sweden, UK
Approvals 2002	New Zealand
Approvals 2003	Australia, Switzerland, Malta
Pending marketing applications	Brazil, Czech Republic, Hungary, Slovenia, South Africa, US, Mexico
Marketing applications planned for 2004	New EU countries, Argentina, Portugal, Netherland
Launches 2001	Sweden
Launches 2002	Denmark, Finland, Norway
Launches 2003	Germany, New Zealand, UK
Scheduled launches 2004	Italy, Spain, Belgium, Switzerland, Australia





Hexvix, PhotoCure's second most advanced pharmaceutical product, is developed for diagnosis and treatment of bladder cancer. In the diagnostic procedure, the patient's bladder is filled with a Hexvix solution that is left in the bladder for 30-60 minutes. During this time, photoactive porphyrins accumulate selectively in the malignant tissue. When the bladder is emptied and illuminated with blue light, the photosensitiser fluoresces in red, making the cancer cells clearly visible. In order to treat bladder cancer, a stronger light can be used to activate the photosensitiser and destroy the cancerous cells. Alternatively, the fluorescence can be used as a guide in conventional surgery to outline the exact location of the cancer and thus ensure complete removal.

**D**uring 2003, Hexvix has taken a big step closer to commercialisation. In the first half of 2003, a collaboration agreement was established between PhotoCure and Karl Storz (Germany), a leading manufacturer of cystoscopes. The goal of the collaboration is to elaborate a joint marketing application in the US for Hexvix and Karl Storz' D-light system. Moreover, another European clinical phase III study generated promising results for the detection of bladder cancer, and in September, PhotoCure received positive preliminary feedback from the Swedish authorities regarding the marketing authorisation application for Hexvix.

### Diagnosis and Treatment of Bladder Cancer

The difficulty of identifying bladder cancer at the initial diagnosis and incomplete tumour resection is thought to be the main reason that 50-70% of bladder cancer patients have one or more recurrences after initial therapy. Despite treatment, about 10-30% of these patients experience tumour progression. Better methods for diagnosis and tumour resection are clearly the key to improving the overall prognosis for bladder cancer patients.

Bladder cancer is currently diagnosed by white light cystoscopic examination, including biopsies and detection of cancer cells in the urine. Diagnosing tumours involves the insertion of a cystoscope into the patient's bladder for visual examination of the bladder walls. Pre-malignant tissue and carcinoma in situ (CIS) is particularly difficult to identify using this method due to its "flat" appearance. In order to diagnose or rule-out bladder cancer, approximately 4.5 million cystoscopic bladder

inspections are performed in Europe and the US each year.

Current treatments for bladder cancer include transurethral resection of bladder (TURB), cystectomy and local and systemic drug therapy. TURB involves surgical removal of tumours, but due to the high recurrence rate, it is often combined with local drug therapy.

### Hexvix can Improve the Diagnosis and Treatment of Bladder Cancer

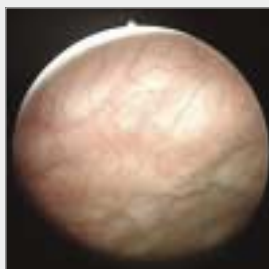
PhotoCure's proprietary Hexvix imaging is designed to significantly improve the physician's ability to identify cancerous and pre-cancerous lesions. The diagnostic procedure involves filling the patient's bladder with Hexvix solution for 60 minutes before examination. Hexvix accumulates in the cancerous cells and when illuminated with blue light, emits a red fluorescence colour that makes the tissue clearly visible to the physician.

Hexvix photodynamic therapy could be carried out as a supplement or an alternative to both TURB and to intravesical pharmacotherapy, by illuminating the bladder with an appropriate light source in order to activate Hexvix. This activation leads to the production of singlet oxygen that destroys the cancer cells.

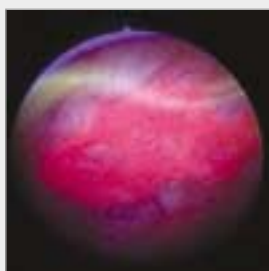
### Hexvix Closer to Commercialisation

In December 2002, the first marketing authorisation application for Hexvix for detection of bladder cancer was submitted in Sweden and in September 2003, PhotoCure received the first feedback from the Swedish authorities. The feedback was positive. An approval of the Swedish application may pave the way





*The bladder inspected with standard white cystoscopy*



*A cancer lesion (carcinoma in situ) detected only when Hexvix fluorescence cystoscopy is employed*

for marketing authorisations in the remaining EU/EAA countries.

PhotoCure is now focussing on pre-launch activities for Hexvix as well as continuing the evaluation of possible partners for sales and marketing outside the Nordic region.

### **Towards Submission of US Application**

Through a collaboration agreement, PhotoCure and Karl Storz GmbH (Tuttlingen, Germany) have agreed to submit a combined marketing application in the US for Hexvix and Karl Storz' D-light system for detection of bladder cancer. Karl Storz is a leading manufacturer of endoscopes, instruments and equipment for use in minimal invasive surgery, including urology, and the D-light system is already approved in Europe.

A previous collaboration with Karl Storz enabled PhotoCure to complete the regulatory application for Hexvix in Europe. The application was based on results from clinical trials with Hexvix and the D-light system conducted in 28 leading urology clinics in Europe.

The US Food and Drug Administration (FDA) has given Hexvix status as an Investigational New Drug (IND), and a comprehensive trial programme is ongoing in the US and Canada, including 19 leading urology clinics.

### **Second Phase III Study Generates Positive Results**

In March, a second European multi-centre phase III study with Hexvix fluorescence cystoscopy was completed. The study set out to determine whether improved detection of

bladder cancer lesions with Hexvix compared to standard white light cystoscopy would lead to better treatment for the patients, and the results are very positive. Hexvix imaging detected 96% of all lesions, while only 77% of the lesions were detected using white light. This led to an improved patient management in 25% of the patients with bladder cancer. The study showed that Hexvix was considered useful by the urologists in diagnosing bladder tumours in 78% of the patients and that it was beneficial in determining further patient treatment in 42% of the patients.

The study took place at ten university clinics in Germany and the Netherlands, and included 146 patients with known or suspected bladder cancer. The positive results from this second phase III trial support the first European phase III study, which concluded that Hexvix fluorescence cystoscopy identifies approximately 30% more patients with aggressive bladder cancer (carcinoma in situ) compared to standard cystoscopy.



**PhotoCure is developing Benzvix for the diagnosis and treatment of early-stage cancers of the gastro-intestinal tract, particularly oesophageal and colon cancers. Benzvix works on the same principle as Hexvix and several pilot clinical studies are ongoing.**

**P**hotoCure has estimated that each year in Europe and the US, there are around six million diagnostic procedures carried out for pre-cancerous changes in the oesophagus alone. In the UK, gastro-intestinal cancers account for 25% of all cancers diagnosed. A significant percentage of gastro-intestinal tumours are curable by surgery with or without chemotherapy or radiotherapy. However 50-70% of patients relapse or present with disease too advanced to be cured.

### **Improving Diagnosis and Treatment using Benzvix**

Benzvix was developed to be used in a similar manner to Hexvix and works on the principle of using light illumination for the diagnosis and treatment of lesions. Administered locally to the tumour, Benzvix is left for a period of time, allowing the photosensitiser to accumulate in the cancerous cells. For diagnostic use, the area is illuminated with a blue light to cause red fluorescence of the cancer cells, making them clearly visible to the surgeon. For treatment, the area is illuminated by red light to activate the photosensitive molecules and destroy the pre-cancerous or cancerous cells.

### **Other potential applications for Benzvix**

PhotoCure is also investigating the use of Benzvix for other applications, including the diagnosis and treatment of pre-cancerous and cancerous lesions in the upper airways and in gynaecological indications.

### **Clinical Pilot Studies Ongoing**

PhotoCure has completed one pilot study in patients with colorectal cancer and has initiated new pilot studies. Initial results are positive and PhotoCure will continue to perform studies with the aim of enter into formal clinical trials as soon as possible.

# PCI BIOTECH AS

PhotoCure ASA - Annual Report 2003



PhotoCure's subsidiary, PCI Biotech AS, was established in 2000 to commercialise its proprietary technology, photochemical internalisation (PCI). The PCI-technology addresses the large and rapidly growing drug delivery market. There is a great interest in the pharmaceutical industry for delivery technologies that could improve the efficacy and specificity of existing products, and/or that could extend product life by providing additional patent protection. In addition, the emerging class of therapeutic macromolecules is largely dependent on efficient and specific delivery systems for realization of their great therapeutic potential.

PCI was developed to introduce therapeutic molecules in a biologically active form specifically into diseased cells. Many therapeutic targets of interest are located inside the cell and have, until now, been highly inaccessible for important classes of therapeutic molecules. This is essentially true for new classes of therapeutic macromolecules, such as proteins, oligonucleotides and DNA, but also for some small molecule drugs, e.g. certain cytotoxic agents for cancer treatment. Employing PCI, a technology for light-directed drug delivery, such molecules could be rendered active in the desired area of the body only, potentially making the therapies substantially more specific.

PCI Biotech's short-term business focus is to enter into commercial agreements for selected cancer indications with companies having therapeutic products that can benefit from the PCI delivery technology. In a longer term strategy the PCI technology will be developed for new emerging classes of therapeutic molecules, e.g. macromolecules. Typically such development is expected to be done in collaboration with biotech or pharmaceutical companies developing such molecules.

In addition to cancers, other potential target diseases such as cardiovascular, eye and autoimmune diseases (rheumatoid arthritis) will also be pursued in a long-term strategy. Furthermore, the possibilities for using PCI as a delivery system for DNA vaccines will be explored.

## A Solid Foundation for the Future

PCI Biotech has made significant progress in 2003 in close collaboration with the Norwegian

Radium Hospital (NRH), Northern Europe's largest centre for cancer research and cancer treatment. The efficacy of the technology has been further demonstrated in animal cancer models, and especially good results have been obtained in sarcoma treatment. Studies, largely financed by the NRH, are ongoing towards clinical studies on this disease.

Another important achievement has been the demonstration that PCI can significantly enhance the effect of peptide nucleic acids (PNAs) directed against important cancer therapeutic targets. PNAs are representatives of the large class of "oligonucleotide technologies" that are being developed both for therapeutic and for in vitro approaches. Although promising, the potential of these technologies has still to be realised, mainly because of delivery problems that the PCI technology may be able to solve.

At present, approximately 20 full time scientists at NRH perform research in PCI and related areas. PCI Biotech has all rights for commercial exploitation of new results. In addition, PCI Biotech is collaborating with leading academic groups worldwide for further development of the PCI technology.

## RESEARCH AND DEVELOPMENT



*PhotoCure's light source Aktillite CL 128 has been selected for the 2003 Award for Design Excellence by the Norwegian Design Council.*



**PhotoCure uses a global network of academic institutions and third party contract research organisations to give the Company access to world-class research at an affordable cost.**

**P**hotoCure operates its research and development activities through a "virtual" structure, based on collaborations with a range of academic institutions globally and a number of third party contract research organisations. This approach gives the company access to world-leading research, whilst allowing it to manage development costs prudently and perform the work rapidly. The company has a number of research projects with several institutions. Major and long-term agreements have been entered into with the following:

### **Norwegian Radium Hospital Research Foundation, Norway**

PhotoCure's most important and long-standing research relationship is with the Norwegian Radium Hospital Research Foundation (RF), which is affiliated to the Norwegian Radium Hospital (NRH). The main patents covering Metvix, Hexvix and Benzvix, as well as the PCI-technology, were all filed by NRH. Under the terms of this agreement, PhotoCure supports the RF with research and development funding and gains access to, and an option to acquire all of, the new photodynamic therapy technologies developed by the NRH. In February 2003, the parties entered into a new three-year agreement, in which PhotoCure has a unilateral option to extend the agreement on an annual basis, up to a total of five years. A separate agreement has been entered into between the RF and PCI Biotech, covering the PCI-technology.

### **University of Leeds, UK**

Under the terms of this agreement, PhotoCure funds a research programme at the university for photosensitisers.

### **Swiss Federal Institute of Technology and the Municipal University Hospital in Lausanne, Switzerland**

PhotoCure has an agreement with the Swiss Federal Institute of Technology and the Municipal University Hospital to collaborate in the development of Hexvix. PhotoCure is funding research and has a first right of refusal to intellectual property from the research relating to the use of Hexvix for the diagnosis and treatment of bladder cancer.

### **Drug Discovery Laboratory (DDL), Norway**

DDL assists PhotoCure with the synthesis of new chemical entities for photodynamic therapy and with the intellectual property strategy and implementation under the terms of this cooperation agreement.

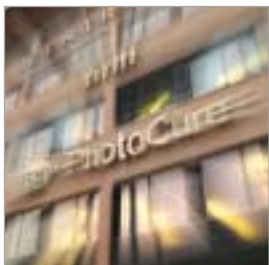
### **Contract Research Organisations (CROs)**

PhotoCure outsources most of its pre-clinical and clinical research and development to a range of CROs. Toxicological studies are conducted in the UK by Covance, a major provider of pre-clinical research services to the pharmaceutical industry. Clinical research and development, such as human trials and statistical data analysis, is undertaken by a range of CROs including Smerud Medical Research (Norway), Clinical Data Care (Sweden), Inveresk Research (UK/US), Parexel (UK/Germany) and PPD Development (UK/US).

All of PhotoCure's research and development partners comply with applicable international standards such as Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP).

# DIRECTORS' REPORT

PhotoCure ASA - Annual Report 2003



**S**ales of Metvix®, PhotoCure's product for the treatment of skin cancer, doubled in the Nordic region in 2003. At the same time, Galderma S.A, PhotoCure's global sales and marketing partner, started to launch Metvix in the first of the countries that make up its marketing area. The launch of Hexvix®, PhotoCure's product for the detection of bladder cancer, is now approaching, with final approval from the Swedish Medicines Authorities expected in 2004.

Total operating revenues more than doubled in relation to 2002, amounting to NOK 60.3 million in 2003. At the same time, considerable reductions in costs were achieved, and the total net loss was reduced from NOK 96.0 million in 2002 to NOK 42.8 million in 2003.

## Increasing sales of Metvix

During 2003, sales of Metvix doubled in the Nordic region. Total sales and milestone revenues for Metvix on all markets amounted to NOK 55.2 million – more than double the revenues generated in 2002. In the Nordic region, a total of 255 light sources have now been installed at 171 clinics.

In 2003, Galderma initiated launch of Metvix in Germany, United Kingdom and New Zealand.

As part of the European marketing strategy, Galderma held two successful launch symposia. Galderma has established a number of training centres in Germany and United Kingdom. The company also performs installation of Aktilite lamps and provides the clinics with support for initial treatments with Metvix. Galderma is pleased with the clinical acceptance Metvix has received in Germany and United Kingdom.

## Introducing Metvix to new markets

During 2003, Metvix was granted marketing approval in Switzerland and Australia for the treatment of premalignant skin conditions (actinic keratosis, AK) and skin cancer (basal cell carcinoma, BCC). Metvix is now approved for sale and marketing in 16 European countries as well as Australia and New Zealand.

Galderma is planning to launch Metvix in Italy, Spain, Belgium, Australia and Switzerland in 2004. In addition, applications for marketing approval have been submitted in the Czech Republic, Hungary, Slovenia, South Africa, Brazil and Mexico, and in 2004 applications will be filed in Portugal, the Netherlands, Argentina and other new countries that will be joining to the EU this year.

PhotoCure has previously received feedback from the US regulatory authorities (Food and Drug Administration, FDA) stating that the Metvix application for the treatment of actinic keratosis was approvable. In 2003, PhotoCure answered questions posed by the FDA in connection with this application, and final approval is expected in the first half of 2004. In 2003, PhotoCure also applied for approval of Metvix for primary treatment of nodular basal cell carcinoma in the United States. In September, this

application was evaluated by an advisory committee to the FDA. The committee recommended that additional information was necessary in order to recommend approval of Metvix for this indication. The FDA subsequently reached the same conclusion. PhotoCure is currently communicating with the FDA with the aim to obtain approval for treatment of basal cell carcinoma.

## Metvix suitable for new indications

Ongoing clinical trials with Metvix are showing promising results in the treatment of early squamous cell carcinoma. Compared with standard methods of treatment, Metvix produced better clinical and cosmetic results. Metvix has also proved effective in the treatment of actinic keratosis and early squamous cell carcinoma in organ transplant patients with suppressed immune systems, and there is reason to believe that treatment with Metvix may prevent new skin lesions in these patients. The total number of transplant patients worldwide is estimated at 400,000. This represents a great market potential as lesions are frequently observed in such patients.

## Hexvix approaching its launch

The first marketing approval for Hexvix – PhotoCure's product for the detection of urinary bladder cancer – is expected in 2004, after PhotoCure received its first positive response from the Swedish Medicines Authorities in September 2003. The only remaining issue with the Swedish Medicines Authorities, is a limited pharmacokinetic study. Approval in Sweden will pave the way for approvals from other EU/EEA countries. In the United States, a clinical phase III study is currently underway as part of the preparations for the submission of an US marketing application.

Using the current standard methods for diagnosing bladder cancer (white light cystoscopy), a considerable number of early-stage tumours remain undetected, and this can lead to inadequate treatment with a high risk of the condition worsening. Bladder cancer is a dangerous illness with a high level of mortality if the cancer is allowed to develop without good treatment at an early stage. Hexvix imaging (blue light cystoscopy) has proved capable of detecting many more tumours, thus leading to better treatment. The method is simple to use and can easily be introduced as a supplement to the current standard method. All that is required is a limited investment in new equipment (blue light system) to complement the existing cystoscopy equipment. Hexvix can also be used as an aid to fluorescence-based surgery.

The market potential for Hexvix is considerable. Every year, more than four million cystoscopy examinations are performed to detect possible bladder cancer in Europe and the United States, and each year, almost 200,000 cases of bladder cancer are discovered in the same regions.

Hexvix is also being developed for treatment of bladder cancer. When the light-sensitive molecules in Hexvix are activated with a stronger light source, the cancer cells will be destroyed. PhotoCure has started a clinical pilot study involving Hexvix as a treatment for bladder cancer, and the results so far are encouraging.

### **Commercialisation of Hexvix**

In addition to following up on the first marketing application for Hexvix, PhotoCure is currently focusing on the preparations for launch of Hexvix while simultaneously continuing to

evaluate potential partners for the sale and marketing of this product outside the Nordic region.

PhotoCure presented clinical data at the annual congress of the American Urology Association in Chicago – an event attended by 12,000 urologists. PhotoCure also held a satellite symposium during the Scandinavian urologists' congress in Bergen. Here, too, clinical data were presented.

PhotoCure and Karl Storz have signed a formal collaboration agreement for the development of Hexvix in conjunction with Karl Storz' D-light system (blue light cystoscopy), which has already been approved in Europe. The two products are to be tested together for the diagnosis of bladder cancer with a view to obtaining joint marketing approval for the United States.

### **PCI Biotech continues “drug delivery” research**

PCI Biotech AS is developing a new technology for delivering large therapeutic molecules to diseased cells. This product development is targeted at the large and rapidly expanding market in the field of “drug delivery”. Within the pharmaceutical industry, there is a great deal of interest in technologies that can improve the efficiency and selectivity of existing products. In addition, new and large therapeutic molecules are heavily dependent on efficient and accurate drug delivery systems to realise their full potential.

### **Financial position**

The total operating revenues for the PhotoCure group in 2003 amounted to NOK 60.3 million, up from NOK 28.7 million in 2002. This increase is attributable to a rise in sales as well

as a milestone payment from Galderma in the amount of NOK 16.1 million. The Group generated an operating loss of NOK 53.7 million in 2003. The corresponding figure for 2002 was a loss of NOK 109.5 million. The reduction of the operational loss is due to increased revenues and lower R&D costs. All R&D costs in 2003 have been expensed.

Net financial income totalled NOK 10.9 million in 2003, down from NOK 13.5 million in 2002. This is due to a reduction in liquid funds and to lower interest rates. The Group's loss amounted to NOK 42.8 million in 2003. The corresponding figure for 2002 was a loss of NOK 96.0 million. PhotoCure ASA (the parent company) generated a net loss of NOK 38.7 million in 2003, compared to a net loss of NOK 86.3 million in 2002. The Board of Directors of PhotoCure ASA proposes that the net loss be covered by a transfer from other equity capital. After this transfer, available equity capital will amount to NOK 151.6 million, of which NOK 84.7 million will be distributable reserves. The Group's equity capital amounted to NOK 131.9 million as of 31.12.2003, giving an equity ratio of 56.5 percent.

The Group has adopted a cautious investment strategy for its liquid funds. These are invested in bank deposits and money market funds with maturity periods of up to one year. The yield on the company's liquid funds is dependent on money market interest rates and may therefore vary over time. As at 31 December 2003, the Group's liquid funds amounted to NOK 185.8 million. Net cash flow from operations amounted to NOK -70.5 million in 2003, compared to NOK -50.9 million in 2002. PhotoCure received EUR 12 million in 2002 as a result of the signing

of the licence agreement with Galderma. Costs and revenues of the PhotoCure Group accrue in different currencies. To a certain extent, therefore, the Group is vulnerable to the effects of exchange rate fluctuations. The associated risks are continuously evaluated.

It is confirmed that the assumption that the company is a going concern is true and the annual financial report is made in accordance with that. Since the end of the 2003 financial year, there have been no events, other than those stated in this report, of major significance to an evaluation of the company's financial conditions and results.

### Organisation

PhotoCure has its offices in Oslo. At the end of 2003, the PhotoCure Group had 40 employees, five of whom were employed in the subsidiary PCI Biotech AS. The PhotoCure Group makes extensive use of external suppliers for production, research and development, as well as regulatory work. The working environment in the company is considered to be good. No accidents or injuries were registered in 2003. Absence from work due to illness in 2003 totalled 230 working days, equivalent to 2.7 percent of total working days.

PhotoCure's goal is to be a workplace that provides equal opportunities for men and women. The Group aims to ensure that no

employees are discriminated on account of gender in areas such as salary, promotion or recruitment. The company has traditionally recruited from environments in which men and women are relatively evenly represented. Of the company's 40 employees, 19 are women and the distribution of men and women is balanced in most areas. Women are represented on the Board of Directors and on the management of PhotoCure. The average annual salary is higher for men than for women. This is due to the proportion of women in executive positions being lower than that of the men, to a generally higher level of education among the men and to longer average seniority for the men employed by the company. Working hours arrangements in the company are not dependent on gender.

The company does not pollute the external environment.

### Other matters

In April 2002, PhotoCure ASA filed papers in an Australian court to invalidate patent no. 624985 assigned to Queen's University in Kingston, Canada. The patent is licensed to DUSA Pharmaceuticals, Inc. and relates to a method for photodynamic therapy using 5-aminolevulinic acid. In the papers submitted to the court, PhotoCure asserts that publications predating the Queen's University patent preclude the patenting of 5-aminolevulinic acid for photodynamic therapy. DUSA has filed a cross-claim in the same proceeding.

### Future prospects

PhotoCure's primary focus in 2004 will be to work with Galderma to ensure the commercial success of Metvix. Preparing the launch of Hexvix will also be a primary focus.

In the Nordic region, PhotoCure will concentrate on establishing new Metvix clinics, providing support to existing clinics and increasing general awareness of Metvix among health care personnel and patients. Galderma will during 2004 implement comprehensive marketing activities and start new launches outside the Nordic region. PhotoCure expects to receive final approval for Metvix for use in treating actinic keratosis in the United States within the first six months of 2004.

Approval of Hexvix in Sweden, expected in 2004, will pave the way for approvals in other countries of Europe. PhotoCure is preparing the launch of Hexvix and is placing emphasis on the work to conclude an agreement with a partner for the sale and marketing of Hexvix outside the Nordic region.

The commercialisation of Metvix is well underway, and the launch of Hexvix is approaching. PhotoCure would nevertheless like to draw attention to the inherent risks associated with the development and commercialisation of its products.

Oslo, 24 February 2004

Erik Engebretsen, *Chairman of the Board*

Per-Olof Mårtensson, *Deputy Chairman*

Halvor Bjerke, *Member of the Board*

Lars Lindegren, *Member of the Board*

Birgit Agneta S. Norinder, *Member of the Board*

Vidar Hansson, *President and CEO*



# INCOME STATEMENT

## PhotoCure ASA

(Amounts in NOK 000's)

Parent				Group		
2003	2002		Note	2003	2002	2001
		<b>Operating revenues</b>				
55 139	25 223	Sales and milestones revenues	1	55 154	25 223	2 330
2 350	2 344	Other operating revenues	1	5 150	3 486	3 022
<b>57 489</b>	<b>27 567</b>	<b>Total operating revenues</b>		<b>60 304</b>	<b>28 709</b>	<b>5 352</b>
		<b>Operating expenses</b>				
9 514	5 832	Cost of goods sold	4	9 514	5 832	0
24 492	15 273	Payroll expense	2,3	27 756	18 795	25 737
1 661	1 253	Ordinary depreciation	5	1 677	1 269	758
71 436	105 713	Other operating expenses	6,7	75 012	112 339	106 723
<b>107 103</b>	<b>128 071</b>	<b>Total operating expenses</b>		<b>113 959</b>	<b>138 235</b>	<b>133 218</b>
<b>-49 614</b>	<b>-100 504</b>	<b>Operating income</b>		<b>-53 655</b>	<b>-109 526</b>	<b>-127 866</b>
		<b>Financial income and expense</b>				
13 992	20 978	Interest income	8	14 014	20 271	27 486
-3 083	-6 743	Interest expense	8	-3 126	-6 750	-1 308
<b>10 909</b>	<b>14 235</b>	<b>Net financial income</b>		<b>10 888</b>	<b>13 521</b>	<b>26 178</b>
<b>-38 705</b>	<b>-86 269</b>	<b>Loss before tax</b>		<b>-42 767</b>	<b>-96 005</b>	<b>-101 688</b>
0	0	Tax expense	9	0	0	0
<b>-38 705</b>	<b>-86 269</b>	<b>Net loss for the year</b>		<b>-42 767</b>	<b>-96 005</b>	<b>-101 688</b>
		Incl. minority interest in the amount of		-441	-906	-1 074
		Net loss per share	10	-2.44	-5.51	-5.93

# BALANCE SHEET AS OF 31 DECEMBER

PhotoCure ASA - Annual Report 2003

<b>PhotoCure ASA</b>					
(Amounts in NOK 000's)					
<b>Parent</b>			<b>Note</b>	<b>Group</b>	
<b>2003</b>	<b>2002</b>			<b>2003</b>	<b>2002</b>
		<b>Fixed assets</b>			
		<b>Machinery and equipment</b>			
3 221	4 724	Machinery and equipment	5	3 222	4 742
		<b>Financial fixed assets</b>			
1 710	1 512	Accrued pension plan assets	3	1 582	1 429
23 859	5 019	Investment in subsidiary	11	0	0
6 250	6 250	Investment in shares	11	6 250	6 250
<b>31 819</b>	<b>12 781</b>	<b>Total financial fixed assets</b>		<b>7 832</b>	<b>7 679</b>
<b>35 040</b>	<b>17 505</b>	<b>Total fixed assets</b>		<b>11 054</b>	<b>12 421</b>
		<b>Current assets</b>			
		<b>Inventory</b>			
23 124	26 089	Inventory	4	23 167	26 132
		<b>Receivables</b>			
5 782	2 081	Accounts receivable		5 782	2 081
11	11 802	Receivables from group companies	18	0	0
5 609	7 060	Other receivables		7 554	8 869
<b>11 402</b>	<b>20 943</b>	<b>Total receivables</b>		<b>13 336</b>	<b>10 950</b>
		<b>Investments</b>			
170 309	215 414	Securities	12	170 309	215 414
		<b>Cash and cash equivalents</b>			
11 815	32 752	Cash and cash equivalents	13	15 536	34 089
<b>216 650</b>	<b>295 198</b>	<b>Total current assets</b>		<b>222 348</b>	<b>286 585</b>
<b>251 690</b>	<b>312 703</b>	<b>Total assets</b>		<b>233 402</b>	<b>299 006</b>

# BALANCE SHEET AS OF 31 DECEMBER

## PhotoCure ASA

(Amounts in NOK 000's)

Parent			Note	Group	
2003	2002			2003	2002
<b>Equity</b>					
<b>Paid-in capital</b>					
8 789	8 723	Share capital	14,15	8 789	8 723
58 108	52 291	Additional paid-in capital	14	58 108	52 291
2 970	3 880	Other paid-in capital	14	2 970	3 880
<b>69 867</b>	<b>64 894</b>	<b>Total paid-in capital</b>		<b>69 867</b>	<b>64 894</b>
<b>Retained earnings</b>					
81 719	120 424	Retained earnings	14	61 577	102 105
<b>Minority interest</b>					
		Minority interest	14	453	0
<b>151 586</b>	<b>185 318</b>	<b>Total equity</b>		<b>131 897</b>	<b>166 999</b>
<b>Liabilities</b>					
<b>Other long term liabilities</b>					
13 519	17 879	Other long term liabilities	16	13 519	17 879
<b>Current liabilities</b>					
8 325	14 057	Accounts payable		8 571	17 714
2 205	2 223	Employee withholding taxes and social security tax		2 458	2 456
63 839	79 473	Deferred income	1	63 839	79 473
12 216	13 753	Other current liabilities	17	13 118	14 485
<b>86 585</b>	<b>109 506</b>	<b>Total current liabilities</b>		<b>87 986</b>	<b>114 128</b>
<b>100 104</b>	<b>127 385</b>	<b>Total liabilities</b>		<b>101 505</b>	<b>132 007</b>
<b>251 690</b>	<b>312 703</b>	<b>Total equity and liabilities</b>		<b>233 402</b>	<b>299 006</b>

Oslo, 24 February 2004

The Board of Directors of PhotoCure ASA

Erik Engebretsen  
*Chairman of the Board*

Per-Olof Mårtensson  
*Deputy Chairman*

Halvor Bjerke  
*Member of the Board*

Lars Lindegren  
*Member of the Board*

Birgit Agneta S. Norinder  
*Member of the Board*

Vidar Hansson  
*President and CEO*

# CASH FLOW STATEMENT

PhotoCure ASA - Annual Report 2003

## PhotoCure ASA

(Amounts in NOK 000's)

Parent			Group		
2003	2002	Note	2003	2002	2001
<b>Cash flow from operations</b>					
-38 705	-86 269	Loss before taxes	-42 767	-96 005	-101 688
1 661	1 253	Ordinary depreciation	1 677	1 269	758
19	0	Gain on sale of machinery and equipment	19	0	-21
-198	266	Change in pension liability	-153	383	-746
640	-1 244	Remaining items	640	-1 244	0
2 965	-21 802	Change in inventory	2 965	-21 845	-4 287
-3 701	-2 081	Change in accounts receivables	-3 701	-1 940	89
-5 732	14 057	Change in accounts payables	-9 143	9 784	-4 121
-15 634	79 473	Change deferred income	-15 634	79 473	0
-11 512	-35 290	Change in other short-term items	-4 409	-20 781	15 396
<b>-70 198</b>	<b>-51 637</b>	<b>Net cash flow from operations</b>	<b>-70 506</b>	<b>-50 906</b>	<b>-94 620</b>
<b>Cash flow from investments</b>					
-381	-3 887	Investments in machinery and equipment	-381	-3 887	-1 496
204	0	Sales of fixed assets (sales price)	204	0	132
0	-19	Investment in subsidiary	0	-19	0
		11			
-1 250	-5 000	Investments in other companies	-1 250	-5 000	0
<b>-1 427</b>	<b>-8 906</b>	<b>Net cash flows from investing activities</b>	<b>-1 427</b>	<b>-8 906</b>	<b>-1 364</b>
<b>Cash flow from capital transactions</b>					
0	0	New loans	0	0	506
-300	0	Payment on loans	-300	0	-300
5 883	4 136	Paid-in equity	8 575	4 137	1 273
<b>5 583</b>	<b>4 136</b>	<b>Net cash flow from capital transactions</b>	<b>8 275</b>	<b>4 137</b>	<b>1 479</b>
<b>-66 042</b>	<b>-56 407</b>	<b>Net change in cash during the year</b>	<b>-63 658</b>	<b>-55 675</b>	<b>-94 505</b>
<b>248 166</b>	<b>304 573</b>	<b>Cash and cash equivalents as of 01.01</b>	<b>249 503</b>	<b>305 178</b>	<b>399 683</b>
<b>182 124</b>	<b>248 166</b>	<b>Cash and cash equivalents as of 31.12</b>	<b>185 845</b>	<b>249 503</b>	<b>305 178</b>
			13		

# NOTES TO FINANCIAL STATEMENTS FOR 2003

The notes to the financial statements include both the PhotoCure Group and the parent company PhotoCure ASA ("Company"), and are representative of both except where explicitly indicated.

## ACCOUNTING PRINCIPLES

The accompanying financial statements are presented in accordance with the Accounting Act of 1998 (the "Accounting Act") and generally accepted accounting principles in Norway.

### Consolidation principles

The group accounts include the parent company PhotoCure ASA and its subsidiaries, i.e. companies in which the parent company directly or indirectly owns more than 50 percent or has power to control.

The group accounts indicate the cumulative financial net loss and position of the economic entity consisting of PhotoCure ASA and its subsidiaries. The subsidiaries are consolidated on a line-by-line basis within the group accounts. The minority's share of net loss after tax is presented as a separate line item. Share of net loss is normally calculated based on subsidiary net loss after tax as this is entered in the group accounts after eliminations. Negative minority share is recognised as a reduction to retained earnings.

Uniform principles have been utilised in the preparation of group accounts. All significant group transactions and intercompany balances have been eliminated.

The subsidiaries appear at cost within the parent company accounts.

### Consolidation

Acquisition of entities is recognized on the basis of the acquisition method unless otherwise stated. The acquisition method prescribes that the entity's assets and liabilities that exist at the date of acquisition are recorded at fair value. Consideration exceeding that, which relates to identifiable assets and liabilities is classified as goodwill. For partially owned subsidiaries, the minority's share of excess values is included in identified assets and liabilities in the balance sheet. The minority owners' share of excess values is included in minority interests in the group's equity.

### Revenue recognition

Revenues relating to products under development are recognised upon delivery, i.e. at the point of transfer of both the majority of risk and control. Estimated returns are recognised as a reduction to revenues.

Payment in connection with signing of licensing agreement is recognised over the minimum contract period, and milestones related to regulatory approvals and product launches relating to license agreements, are recognised upon achievement.

Royalty revenues are recognised upon licensee's sale of licensed products.

### Research and development

All costs related to research and development until marketing approval is obtained for the product in each country, are expensed as incurred. Acquisitions of independent research and development projects are capitalised as intangible assets provided the conditions for capitalisation are fulfilled.

### Contributions from the government

Contributions received from the government are recognised at the value of the contributions at the transaction date. Contributions are recognised in the statement of operations in the same period as the corresponding revenues or costs. Contributions are not recognised until fulfilment of the relevant conditions is considered probable. Contributions are classified as other operating income within the income statement.

Contributions from the government that are subject to a conditional repayment clause are recognised as a liability, and repayments in the form of royalty etc., are recognised as instalments.

### Assessment of balance sheet items

Unless otherwise stipulated, the following principles are applied:

Assets relating to the operating cycle, as well as receivables due within one year from the time of acquisition are classified as current assets. Other assets are classified as fixed assets. The same principle is applied to the classification of liabilities. Long-term debt that matures within one year is therefore classified as current liability.

Current assets are valued at the lower of cost or market value. Current liabilities are recognised at cost.

Fixed assets are valued at purchase price. Fixed assets are written down to market value in the event of value impairment not considered to be temporary, in accordance with generally accepted accounting principles. Such

write-downs are reversed when the conditions causing to the impairment in value are no longer present. Long-term debt is recognised at the face value.

### Currency

Monetary items in foreign currency are translated at prevailing rates as of the balance sheet date. Realised and unrealised currency gains and currency losses are included within net loss. Transactions in foreign currencies are recorded at prevailing rates as of the transaction date.

### Receivables

Account receivables and other receivables are presented at face value less a provision for doubtful accounts. The provision is based on an evaluation of the realisable value of the individual receivables.

### Current investments

Securities are placed in a money market fund with a life of less than one year in underlying securities. Money market funds are carried at market value.

### Inventory

Stock of purchased inventory is valued on the basis of the lower of cost or market, and on the basis of the first in-first out principle. Inventory relating to products under development are expensed as incurred.

### Fixed and intangible assets

Fixed and intangible assets are capitalised and depreciated on a straight-line basis over the estimated useful life. Expenditures for maintenance and repair costs are expensed as incurred as operating costs. Expenditures for improvements are capitalised and depreciated

at the same rate as the underlying asset.

Write-downs of plant and equipment are made upon identification of a decrease of value, which is not considered to be temporary. If the need for write down is identified, the asset is written down to the lower of book value and net realisable value. Best estimate is utilised in connection with the determination of net realisable value. Assets are grouped and evaluated on the basis of the lowest level of aggregation of identifiable and independent cash flows. Prior write-downs may be reversed to the extent that the basis for the write-down is no longer present.

### Pensions

Pension costs and pension liabilities are calculated straight line on the basis of an assumed discount rate, rate of salary progression, pension and social benefit allowances, rate of return on plan assets, and actuarial assumptions on mortality, early retirement, etc. Pension assets and liabilities appear as a net amount in the financial statements. Changes in pension liability arising from changes in pension plan benefits are recognised over the expected remaining earning period. Changes in pension liabilities and pension funds that are due to changes in the assumptions used are recognised over the expected remaining earning period if the change value as of the beginning of the year exceeds ten percent of the greater of the gross pension plan assets or liability (Corridor). Only the part of the change value exceeding ten percent is amortised.

Social security tax is accrued on the net pension liability.

Net period pension expense appears as an element of salary expense, and consists of

the periods earned pension, interest expense on pension liability, and expected return on pension assets.

### Share options and warrants

Options/warrants are issued to employees at exercise prices, which reflect, at a minimum, market value at the time of issuance, and therefore have no intrinsic value at the time of issuance. Options/warrants are not discounted to reflect time value. Social security taxes relating to additional compensation expense are treated similarly.

Warrants issued to non-employees are recognised at fair market value and are accrued on the basis of the underlying agreement.

### Taxes

Tax expense is comprised of taxes payable for the current period and the change in deferred taxes. Deferred taxes are calculated at 28% of the temporary differences that exist between tax and accounting values, and tax operating loss carry forwards. Tax assets and liabilities resulting from temporary timing differences that reverse or may be reversed in the same periods are offset against one another. Recognition of a deferred tax asset is subject to probable future application.

### Cash flow statement

The cash balance is defined as the total of cash, bank deposits, and money market funds. The cash flow statement is based on the indirect method.

### Equity transactions

Expenditures relating to stock issuance are recognised as a reduction of stock issuance proceeds.

## Net loss per share

Net loss per share is calculated by dividing net loss related to weighted average common stock outstanding during the period. Diluted net loss per share also reflects outstanding options.

## IFRS implementation

All companies listed on the Oslo Stock Exchange must from 1 January 2005 present financial statements complying with the International Financial Reporting Standards (IFRS) from IASB. Financial disclosures in 2005 must include comparative amounts for 2004. In 2003, the Company has appointed a project manager responsible for identifying the consequences for the Company of a transition from generally accepted accounting principles in Norway to accounting principles based on IFRS. IFRS is under continuous development and changes must be anticipated until implementation in 2005. The assessment of possible consequences of the IFRS implementation is therefore preliminary. Based on current IFRS we have identified differences between generally accepted accounting principles in Norway and IFRS with regard to pensions and share-based payments. If a reasonable level of accuracy can be obtained, the Company will seek to quantify these differences in a note to financial accounts for 2004. Financial statements for first quarter 2005, will probably be the first disclosure of financial statements complying with IFRS. PhotoCure will also assess the option given by IFRS to present expenses in the income statement by their function within the enterprise in addition to a classification based on their nature.

## NOTE 1 - OPERATING REVENUES

Sales and milestones revenues relate to sales of products, royalties, earned signing income and milestones payments. All revenues originate from the same area, including research, development, production and sales of pharmaceutical products and associated medical technical devices. Earned signing fee in the amount of NOK 15.6 million is included in sales and milestones revenues in 2003 and NOK 14.3 million in 2002. The remaining NOK 63.8 million of the signing fee are included as deferred income in the balance sheet as of 31 December 2003. Milestones payments in the amount of NOK 16.2 million are included in sales and milestones revenues in 2003. Other operating income includes public contributions in the amount of NOK 4.8 million for 2003 and NOK 3.2 million for 2002 to the group and NOK 1.6 million for 2003 and 2002 to the parent company.

## NOTE 2 - LABOUR COSTS, ADDITIONAL COMPENSATION COSTS, NUMBER OF EMPLOYEES, ETC

(Amounts in NOK 000's)

	Group			Parent	
	2003	2002	2001	2003	2002
Wages	20 269	18 226	14 463	17 866	15 650
Social security tax	4 210	3 156	2 591	3 839	2 780
Social security tax employee share options	256	-6 127	5 547	256	-6 127
Pension expense	1 932	2 041	992	1 628	1 606
Other compensations	1 089	1 500	2 144	903	1 364
<b>Total labour costs</b>	<b>27 756</b>	<b>18 796</b>	<b>25 737</b>	<b>24 492</b>	<b>15 273</b>
Average number of employees (weighted)	36.7	34.8	28.3	32.5	29.4

<b>Compensation to CEO and Board of Directors (BoD)</b>	<b>CEO</b>	<b>BoD</b>
Wages	1 479	1 136
Pension premium	99	
Other compensations	9	

The Company's President and CEO may, under certain conditions, claim compensation for a maximum of eighteen months beyond the dismissal period. If the President and CEO receives other compensation for his services during the eighteen-month period, the amount of other compensation received will be deducted from the compensation to be paid by the Company. The Company's President and CEO has earned an additional bonus of NOK 2.9 million, payable 1 January 2004. The bonus amount shall be sufficient to cover annual payments of NOK 350,000 (1996 value) each year over a 7-year period. The bonus has been expensed, and is recognised in the balance sheet as other current liability. For additional information, see note 17.



**Subscription rights earned by employees of PhotoCure as of 31.12.2003\*:**

<b>Total subscription rights</b>	<b>Exercise price</b>	<b>Exercise period</b>
76 000	NOK 91-129	01.01.2003 – 31.12.2006
55 329**	NOK 107.50	Up to 1/3 may be exercised at the earliest in 2003, up to 2/3 at the earliest in 2004 and all by 31.12.2005
30 998**	NOK 34.50	Up to 1/3 may be exercised at the earliest in 2004, up to 2/3 at the earliest in 2005 and all by 31.12.2006

\* Conditional award of subscription rights for 2004 is not included in this table.

\*\* Including 31,200 subscription rights earned by the company management, for more information see note 15.

In connection with the Company's incentive policy, all employees have been granted subscription rights to Company stock. Subscription price is at a minimum set at estimated market value at the time of subscription issuance. The Board of Directors has not been issued subscription rights. The Board of Directors has in 2004 continued the incentive program for Company employees, including Company management. 129,050 contingent share options/subscriptions have been be issued for 2004, in which each share option provides a right to subscribe to one share in the Company. Such options will be earned upon the satisfaction of certain benchmark goals as specified within the work program and within the 2004 budget. 1/3 of the share options/subscriptions may be exercised each year starting in 2005 and ending in 2007. All the share options must be exercised by 31 December 2007. Of these subscription rights/share options, 20,000 were issued to the Chief Executive Officer, 10,000 were issued to the Chief Financial Officer, 10,000 were issued to the Vice President of Research and Development and 10,000 were issued to the Vice President of Strategic Marketing.

In connection with the Company's employee co-ownership program, selected employees of PhotoCure ASA have been offered to subscribe shares in the Company, in which portions of payable amounts have been deferred. Upon sale of shares acquired in connection with this program, the Company shall be entitled to the portion of proceeds, which corresponds with the difference between the subscription price and the market value of stock as of the date of subscription. In the event that such stock is held for 10 years, a final settlement, based on the same principles, will be effectuated. In the event that such shares are sold within a specified period, the Company has, on the basis of defined terms, pre-emptive rights. As of 31 December 2003, 25,000 shares were subscribed to in connection with the program (please also refer to note 15).

**Auditor**

The auditor's fee for statutory audit in 2003 was NOK 209,000 for the group and NOK 178,000 for the parent company. Auditor's fees, exclusive of VAT, are specified in the following table:

<b>Auditor's fees: (Amount in NOK 000's)</b>	<b>Group</b>	<b>Parent</b>
Statutory audit	209	178
Audit related services	35	15
Tax related services	84	84
Other services	7	7
<b>Total</b>	<b>335</b>	<b>284</b>

### NOTE 3 - PENSION LIABILITIES

The Group is enrolled in a collective pension arrangement (the "Plan") through Nordea Liv Norge AS.

The Plan is in compliance with Norwegian Standards for Accounting.

The pension benefit calculation is based on the following assumptions:

	2003	2002	2001
Expected long term rate of return on plan assets	7.50 %	7.50 %	7.50 %
Discount factor	6.50 %	6.50 %	6.50 %
Rate of salary progression	3.50 %	3.50 %	3.50 %
Yearly adjustment of G*	3.00 %	3.00 %	3.00 %
Increase in pension benefits	3.00 %	3.00 %	2.50 %

\* G is the basic amount in the National Insurance

Underlying actuarial assumptions relating to demographic factors and terminations are in line with standard, insurance industry guidelines. The calculation is based on coverage of 31 employees in the Group and 26 employees in the parent company.

Current year net periodic pension expense was calculated as follows:

(Amounts in NOK 000's)	Group			Parent	
	2003	2002	2001	2003	2002
Service Cost	1 616	1 732	844	1 362	1 347
Interest Expense	291	223	117	268	207
Actual return on plan assets	-294	-199	-206	-281	-190
Net amortisation and deferral	47	91	31	53	86
Social security tax	272	194	206	226	156
<b>Net pension expense</b>	<b>1 932</b>	<b>2 041</b>	<b>992</b>	<b>1 628</b>	<b>1 606</b>

Pension liability:

(Amounts in NOK 000's)	Group		Parent	
	31.12.2003	31.12.2002	31.12.2003	31.12.2002
Projected benefit obligation	-6 378	-5 383	-5 753	-4 733
Plan assets at fair value	6 787	5 011	6 233	4 544
Unrecognised net loss	1 183	1 797	1 230	1 701
<b>Net plan assets before social security tax</b>	<b>1 592</b>	<b>1 425</b>	<b>1 710</b>	<b>1 512</b>
Social security tax	-10	4	0	0
<b>Accrued plan assets (liabilities)</b>	<b>1 582</b>	<b>1 429</b>	<b>1 710</b>	<b>1 512</b>

**NOTE 4 - INVENTORY**

<i>(Amounts in NOK 000's)</i>	Group		Parent	
	31.12.2003	31.12.2002	31.12.2003	31.12.2002
Raw materials	18 973	20 928	18 973	20 928
Finished goods	4 194	5 204	4 151	5 161
<b>Total inventory</b>	<b>23 167</b>	<b>26 132</b>	<b>23 124</b>	<b>26 089</b>

**NOTE 5 - PLANT AND EQUIPMENT**

<i>(Amounts in NOK 000's)</i>	Group	Parent
	Machinery & equipment	Machinery & equipment
Purchase price 01.01.2003	7 459	7 412
Additions	381	381
Disposals	-267	-267
<b>Purchase price 31.12.2003</b>	<b>7 573</b>	<b>7 526</b>
Accumulated depreciation 01.01	2 718	2 688
Depreciation expense	1 677	1 661
Disposals	-44	-44
Accumulated depreciation 31.12	4 351	4 305
<b>Book value 31.12.2003</b>	<b>3 222</b>	<b>3 221</b>
Book value 01.01.2003	4 741	4 724
Expected economic life	3-5 years	3-5 years
Depreciation method	Linear	Linear

**NOTE 6 - OTHER OPERATING EXPENSES**

<i>(Amounts in NOK 000's)</i>	Group			Parent	
	2003	2002	2001	2003	2002
External research and development costs	38 377	77 300	78 036	35 841	72 378
Marketing expenses	6 535	7 720	10 145	6 407	7 494
Travel expenses	5 634	5 039	4 207	5 509	4 859
Patent and trademark registration fees	11 031	10 032	1 999	9 483	9 422
Other costs	13 435	12 248	12 336	14 196	11 560
<b>Total other operating expenses</b>	<b>75 012</b>	<b>112 339</b>	<b>106 723</b>	<b>71 436</b>	<b>105 713</b>

## NOTE 7 - RESEARCH AND DEVELOPMENT

The Company develops products for treatment of cancer and other diseases. The Company has incurred NOK 38.4 million in externally generated research and development expenses during 2003. Internal research and development costs, such as project manager salaries, etc are not included in the amount above. The Company's management believes that costs related to research and development will be covered by future income from products under development.

## NOTE 8 - FINANCIAL ITEMS

<i>(Amounts in NOK 000's)</i>	Group			Parent	
	2003	2002	2001	2003	2002
Interest income	10 426	18 404	26 407	10 317	18 346
Interest income group	0	0	0	104	782
Foreign exchange gains	3 588	1 867	1 079	3 571	1 850
<b>Total financial income</b>	<b>14 014</b>	<b>20 271</b>	<b>27 486</b>	<b>13 992</b>	<b>20 978</b>

<i>(Amounts in NOK 000's)</i>	Group			Parent	
	2003	2002	2001	2003	2002
Interest expenses	435	459	758	435	459
Foreign exchange loss	2 549	6 120	315	2507	6114
Other financial expenses	142	171	235	141	170
<b>Total financial expenses</b>	<b>3 126</b>	<b>6 750</b>	<b>1 308</b>	<b>3 083</b>	<b>6 743</b>

## NOTE 9 - TAXES

### Tax expense consists of the following:

<i>(Amounts in NOK 000's)</i>	Group			Parent	
	2003	2002	2001	2003	2002
Taxes payable on net income	0	0	0	0	0
Change in deferred tax	0	0	0	0	0
<b>Tax expense</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

### Taxes payable was calculated as follows:

<i>(Amounts in NOK 000's)</i>	Group			Parent	
	2003	2002	2001	2003	2002
<b>Net loss before tax</b>	<b>-42 767</b>	<b>-96 005</b>	<b>-101 688</b>	<b>-38 705</b>	<b>-86 269</b>
Expected nominal rate	-11 975	-26 881	-28 473	-10 837	-24 155
Permanent differences	-720	-840	270	-379	-392
Write down of deferred tax asset	12 695	27 721	28 203	11 217	24 548
<b>Taxes payable on net loss</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

**Specification of the basis for deferred tax assets and liabilities:**

<i>(Amounts in NOK 000's)</i>	Group		Parent	
	2003	2002	2003	2002
<b>Temporary differences:</b>				
Fixed assets	-2 635	-2 514	-2 617	-2 503
Securities	0	1 041	0	1 041
Liabilities	-12 257	-11 763	-12 257	-11 763
Net pension asset	1 582	1 429	1 710	1 512
Loss carry forward	-379 623	-335 791	-354 523	-315 915
<b>Total</b>	<b>-392 933</b>	<b>-347 598</b>	<b>-367 688</b>	<b>-327 628</b>
Deferred tax asset (28%)	-110 021	-97 327	-102 953	-91 736
Deferred tax asset not recognized	110 021	97 327	102 953	91 736
<b>Book value of deferred tax asset</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

**The operating loss carry forward expires according to the following schedule:**

<i>(Amounts in NOK 000's)</i>	Group	Parent
2006	1 121	1 121
2007	6 721	6 721
2008	11 380	11 380
2009	38 430	38 430
2010	73 406	73 153
2011	99 246	90 836
2012	105 163	93 950
2013	44 157	38 933
<b>Total</b>	<b>379 623</b>	<b>354 524</b>

RISK per share amounts to NOK 0 as of 31 December 2002 and is estimated by the Company to amount to NOK 0 as of 31 December 2003.

**NOTE 10 - NET LOSS PER SHARE (GROUP)**

<b>Net loss per share</b>	2003	2002	2001
W.A.S.O.*	17 503 849	17 417 589	17 162 301
Avg. net loss per share	-2.44	-5.51	-5.93
W.A.S.O.* (diluted)**	17 503 849	17 586 161	17 690 939

\* Weighted Average Shares Outstanding

\*\* Excluded from calculation when antidilution results.

PhotoCure had issued 181,329 share options and warrants at the end of 2003.

## NOTE 11 - INVESTMENTS IN SUBSIDIARIES AND OTHER COMPANIES

Company	Location	Year of acquisition	Company share capital 31.12.2003	Ownership and voting share 31.12.2003	Book value 31.12.2003	Equity 31.12.2003	Net income 2003
PCI Biotech AS	Oslo, Norway	2000	NOK 222,000	89.14 %	NOK 23.9 mill	NOK 4.2 mill	NOK -4.1 mill
PhotoCure Australia Pty Ltd	Melbourne, Australia	2000	AUD 12	100.00 %	NOK 0	NOK 0	NOK 0

In 2003, PhotoCure converted NOK 18.8 million in receivables into equity in PCI Biotech AS.

PhotoCure owns 12,500 shares in Algeta AS (formerly Anticancer Therapeutic Inventions AS), corresponding to 6.8% of the company shares. Algeta AS is a Norwegian company that develops radioactive drugs for the treatment of cancer. The shares are recognised at cost price NOK 6.25 million.

## NOTE 12 - SECURITIES

The Company's securities portfolio consists of investments in money market funds, which invest in short term interest bearing securities. Rate of return is in line with the going market rate for similar securities. Investments as of 31 December 2003 were as follows:

(Amounts in NOK 000's)

	Book value	Market value	Return
DnB Asset Management ASA	136 849	136 849	7 932 834
Storebrand Fondene AS	33 460	33 460	1 961 988
<b>Total</b>	<b>170 309</b>	<b>170 309</b>	<b>9 894 822</b>

## NOTE 13 - CASH DEPOSITS

Restricted cash as of 31.12.2003:

(Amounts in NOK 000's)

	Group	Parent
Restricted cash	2 136	2 016

## NOTE 14 - EQUITY

### Equity in parent

(Amounts in NOK 000's)

	Share capital	Share premium reserve	Other restricted capital	Retained earnings	Total parent
<b>Equity as of 31.12.2002</b>	<b>8 723</b>	<b>52 291</b>	<b>3 880</b>	<b>120 424</b>	<b>185 318</b>
Accrued subscription rights			-910		-910
Share issue employees	66	5 817			5 883
Net loss of the year				-38 705	-38 705
<b>Equity as of 31.12.2003</b>	<b>8 789</b>	<b>58 108</b>	<b>2 970</b>	<b>81 719</b>	<b>151 586</b>

**Equity in group***(Amounts in NOK 000's)*

	<b>Total paid-in capital</b>	<b>Retained earnings</b>	<b>Minority interest</b>	<b>Total equity</b>
<b>Equity as of 31.12.2002</b>	<b>64 894</b>	<b>102 105</b>	<b>0</b>	<b>166 999</b>
Equity transactions in parent	4 973			4 973
Share increase in subsidiary			2 692	2 692
Net loss of the year		-42 326	-441	-42 767
Negative minority share transferred to retained earnings		1 798	-1 798	-
<b>Equity as of 31.12.2003</b>	<b>69 867</b>	<b>61 577</b>	<b>453</b>	<b>131 897</b>

**NOTE 15 - SHARE CAPITAL AND SHAREHOLDER INFORMATION**

Registered share capital in PhotoCure ASA was comprised of the following as of 31 December 2003:

<b>Share outstanding</b>	<b>Par value</b>	<b>Book value of share capital</b>
17 577 000	NOK 0.50	NOK 8 788 500

All shares reflect identical rights to the Company, including equal voting rights.

The Board of Directors was authorised by the General Assembly on 3 April 2003 to issue 2.7 million shares, of which (a) 1.8 million shares relates to the financing of the company's development, while issuance of (b) 0.9 million shares relates to issuance of stock to employees and to certain strategic partners. The remaining authorisation as of 31 December 2003 was 2.6 million shares. Authorisation relating to (a) remains effective through the annual general assembly in 2004, while authorisation relating to (b) remains effective through the annual general assembly in 2005. Previously reported authorisations have expired.

The following table provides an overview as to the status of authorisations as of 31 December 2003:

<i>(Amounts in # of shares)</i>	<b>Ordinary share issue</b>	<b>Employee issue</b>
Issue authorisation general assembly 03.04.2003	1 800 000	900 000
Share issues pursuant to general assembly 03.04.2003	0	132 000
<b>Remaining issue authorisation</b>	<b>1 800 000</b>	<b>768 000</b>

In addition, subscription rights to 162,327 shares were issued to employees (see note 2), and remain unexercised, as well to 50,000 shares to strategic partners (see below).

As described in Note 2, selected employees in PhotoCure ASA has been offered share subscriptions, where portions of the payments are deferred. The company will receive a maximum payment of NOK 2.1 million from those who as of 31 December 2003 have acquired shares under this arrangement.



### Subscription rights to non-employees

PhotoCure ASA has entered into a research and development contract in which a strategic partner has been issued subscription rights to 50,000 shares. Such rights may be exercised at a maximum of 12,500 shares per year as of 1 January of each year, for a period of three years, from 1 January 2002 through 1 January 2005, provided that the cooperation agreement is not cancelled. The subscription rights are exercisable through 31 December 2005. The issue price is NOK 125 per share, and the total value of all subscription rights was estimated at NOK 3,135,000 at the time of issuance. The strategic partner assists PhotoCure ASA in the development of new substances and in patenting issues.

The value of subscription rights is calculated on the basis of Black-Scholes model for valuation of options.

### Ownership structure

The primary shareholders in the Company as of 31 December 2003, were:

	Shares	Ownership percentage
Radiumhospitalets Forskningsstiftelse	3 759 000	21.4 %
Gezina AS	960 373	5.5 %
Sundt AS	420 749	2.4 %
Ferd AS Invest	400 000	2.3 %
Vidar Hansson/Varak AS*	373 500	2.1 %
Brown Brothers Harriman & Co	353 200	2.0 %
Sig.Bergesen D.Y. almennyttige stiftelse	352 750	2.0 %
Marlin Verdi AS	345 000	2.0 %
Morgan Stanley and Co Ltd.	325 280	1.9 %
Vicama AS	285 221	1.6 %
Skagen Vekst	250 000	1.4 %
Norsk Hydros Pensjonskasse	249 263	1.4 %
Royal Trust Corporation of Canada	240 200	1.4 %
Sparebankenes sikringsfond	230 000	1.3 %
Bergen Kommunale Pensjonskasse	225 000	1.3 %
J P Morgan Chase Bank	204 213	1.2 %
Gjensidige Nor spareforsikring	194 800	1.1 %
R. Ulstein Loen AS	193 049	1.1 %
Tine Pensjonskasse	176 100	1.0 %
<b>Total with greater than 1% ownership</b>	<b>9 168 549</b>	<b>52.2 %</b>
Total other	8 408 451	47.8 %
<b>Total shares outstanding</b>	<b>17 577 000</b>	<b>100.0 %</b>

\* Includes shares owned by related parties

Shares owned directly or indirectly by members of the Board of Directors, Chief Executive Officer, and management, and related parties to such as of 31 December 2003:

Name	Position	Number of shares	Subscription rights*
Erik Engebretsen	Chairman of the Board	27 000	0
Per-Olof Mårtensson	Deputy Chairman	3 000	0
Halvor Bjerke	Member of the Board	5 550	0
Lars Lindegren	Member of the Board	24 377	0
Birgit Stattin Norinder	Member of the Board	0	0
Vidar Hansson	President and CEO	373 500	14 000
Kjetil Hestdal	VP R&D	122 873	7 000
Geir Christian Melen	CFO	119 792	7 000
Hilde Morris	VP Strategic Marketing	0	3 200
Auditor		0	0

\* Please refer to Note 2 for more information about subscription rights.

## NOTE 16 - OTHER LONG TERM LIABILITIES

The Company has a risk loan outstanding to Innovasjon Norge (formerly the Norwegian Industrial and Regional Development Fund "SND") with a remaining face value of NOK 2.1 million. Ongoing biannual loan instalments of NOK 300,000 commenced 10 July 2003 and will be completed by 10 January 2007. The current floating interest rate is 6.5% p.a.

PhotoCure ASA has previously received a contribution of NOK 10.4 million from Innovasjon Norge. This contribution contains a conditional repayment clause in form of royalties. Conditional royalty payments are based on accumulated sales revenues from the Company's dermatological products over certain levels, earned by the year ending 31 December 2005. Accumulated royalty liability has a NOK 12.5 million cap. The estimated conditional repayment liability is recognised in the balance sheet as of 31 December 2003 as a long-term liability of NOK 12.3 million, despite the fact that complete or partial achievement of the repayment clause is uncertain.

## NOTE 17 - OTHER CURRENT LIABILITIES

<i>(Amounts in NOK 000's)</i>	Group		Parent	
	2003	2002	2003	2002
External research and development expenses	2 806	10 118	2 806	10 118
Provisions for bonuses, holiday allowances, wages	5 484	1 576	5 246	0
Long-term debt within one year from maturity	600	0	600	0
Other accrued costs	4 228	2 791	3 564	3 635
<b>Total other current liabilities</b>	<b>13 118</b>	<b>14 485</b>	<b>12 216</b>	<b>13 753</b>

## NOTE 18 - INTERGROUP BALANCES

<i>(Amounts in NOK 000's)</i>	Parent	
	2003	2002
Other receivables	11	11 802
Other current liabilities	110	0
<b>Total (net)</b>	<b>-99</b>	<b>11 802</b>

## NOTE 19 - RELATED PARTY TRANSACTION

In February 2003, the Company renewed the collaboration agreement with The Norwegian Radium Hospital Research Foundation (RF). Under this agreement, the Company is allowed access to, and an option to obtain, new technology and "know how" within the field of Photodynamic Therapy ("PDT") developed at the Norwegian Radium Hospital (DNR). As consideration, the Company makes financial contributions toward research and development. The new agreement covers a period of three years and gives PhotoCure a unilateral right to extend it annually for two additional years.

During 2003, the Company, under the terms of the contract, made payments in the amount of NOK 2.2 million, research and development services, at arms-length terms, to DNR, via RF.

## NOTE 20 - FINANCIAL RISK

The return on the Company's investments in securities depends on the interest rate ob-

tained in the money market, and may therefore vary significantly over time.

The Company receives income and incurs costs in various currencies. Consequently, the Company is exposed to currency risk. The Company makes continuous assessments as to whether steps should be taken to reduce this risk.

## NOTE 21 - OTHER LIABILITIES

In order to satisfy conditions relating to the going concern assumption, PhotoCure ASA has issued a guarantee, with an upper limit of NOK 8 million, in which the continued operations of its subsidiary PCI Biotech AS are guaranteed through 30 June 2005. The guarantee will expire upon the effectuation of a share increase in which equity of an amount sufficient to ensure the satisfaction conditions relating to the going concern assumption is received.

The company rents office space at Hoffsvæien 48 in Oslo. Yearly rental expenses amount to NOK 2.4 million, including shared costs. Rent

is adjusted yearly to reflect the change in the consumer price index. The effective date of the rental agreement is 1 September 2000, and is mutually binding through 31 August 2005, at which time the agreement expires. PhotoCure ASA has an option to extend the agreement for an additional five years at the going market rate.

#### **NOTE 22 - SIGNIFICANT NON-RECURRING TRANSACTIONS**

On 19 December 2001, PhotoCure ASA entered into a licensing agreement with Galderma S.A. The agreement became effective as of February 2002 and PhotoCure received at the same time EUR 12 million. The agreement provides Galderma with exclusive rights to the global marketing of Metvix® cream and to PhotoCure's light sources relating to photodynamic treatment, outside the Nordic Area.

In connection with this agreement, PhotoCure received EUR 2 million in 2003, and is entitled to an additional EUR 16 million upon the granting of marketing approval, and product launch of Metvix in certain regions. PhotoCure will, in addition to royalty, receive milestone payments from Galderma on the basis of global sales of Metvix in excess of EUR 25 million per year, as well as payment for production of light sources and Metvix. Irrespective of actual sales, PhotoCure is guaranteed significant royalty and milestone payments for the first 5 years following granting of marketing approval of Metvix in the United States.

#### **NOTE 23 - OTHER MATTERS**

In April 2002, PhotoCure filed papers in an Australian court to invalidate Australian patent no. 624985 assigned to Queen's University in Kingston, Canada. The patent is licensed to DUSA Pharmaceuticals Inc. and relates to a method for photodynamic therapy using 5-aminolevulinic acid. In the papers that were filed, PhotoCure asserts that publications, which predate the Queen's University patent precludes the patenting of 5-aminolevulinic acid for photodynamic therapy. DUSA has put forward a cross-claim.

# AUDITOR'S REPORT FOR 2003

## To the Annual Shareholders' Meeting of PhotoCure ASA

We have audited the annual financial statements of PhotoCure ASA as of 31 December 2003, showing a loss of NOK 38,705,000 for the parent company and a loss of NOK 42,767,000 for the Group. We have also audited the information in the Directors' report concerning the financial statements, the going concern assumption, and the proposal for the coverage of the loss. The financial statements comprise the balance sheet, the statements of income and cash flows, the accompanying notes and the consolidated accounts. These financial statements and the Directors' report are the responsibility of the Company's Board of Directors and Chief Executive Officer. Our responsibility is to express an opinion on these financial statements and on other information according to the requirements of the Norwegian Act on Auditing and Auditors.

We conducted our audit in accordance with the Norwegian Act on Auditing and Auditors and auditing standards and practices generally accepted in Norway. Those standards and practices require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. To the extent required by law and auditing standards, an audit also comprises a review of the management of the Company's financial affairs and its accounting and internal

control systems. We believe that our audit provides a reasonable basis for our opinion.

In our opinion,

- the financial statements have been prepared in accordance with law and regulations and present the financial position of the Company and of the Group as of 31 December 2003, and the results of its operations and its cash flows for the year then ended, in accordance with accounting standards, principles and practices generally accepted in Norway
- the Company's management has fulfilled its duty to properly register and document the accounting information as required by law and accounting standards, principles and practices generally accepted in Norway
- the information in the Directors' report concerning the financial statements, the going concern assumption, and the proposal for the coverage of the loss is consistent with the financial statements and comply with law and regulations.

Oslo, 24 February 2004  
ERNST & YOUNG AS

Henning Strøm  
State Authorised Public Accountant (Norway)

Note: The translation to English has been prepared for information purposes only.







PhotoCure ASA is a Norwegian listed company (Oslo Stock Exchange: PHO) that develops and sells pharmaceuticals and medical devices for treatment and diagnosis of cancer and precancerous conditions. The company develops products for different internal cancers, skin cancer and other skin diseases. Metvix is developed for the treatment of basal cell carcinoma (skin cancer) and actinic keratosis (precancerous skin lesions) and is under development and documentation for several other skin diseases. PhotoCure is responsible for sales and marketing of Metvix in the Nordic countries, while its licensee, the global dermatology specialist, Galderma, is responsible for sales and marketing of Metvix in the rest of the world. PhotoCure's second pharmaceutical product Hexvix is under development for bladder cancer. A Marketing Authorisation Application (MAA) for Hexvix for detection of bladder cancer is filed in Sweden and Phase III studies are ongoing in the US.

PCI Biotech AS, a subsidiary of PhotoCure ASA, focuses on the opportunities for photochemical internalisation (PCI) in drug delivery, e.g. in novel cancer therapeutics and gene therapy.

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