

## **First Quarter Report 2004**

Oslo 6<sup>th</sup> of May 2004

### **Continued sales increase**

#### Highlights

- Operating revenues increased to NOK 15.4 million, compared to NOK 11.5 million in the first quarter of 2003. The number of Metvix units sold to pharmacies in the Nordic region increased by 53% compared to the corresponding quarter in 2003.
- Galderma will initiate launch of Metvix in 5 new countries during 2004. Metvix is launched in Germany, UK, New Zealand and the Nordic countries and is approved for marketing in a total of 19 countries.
- Total operating expenses amounted to NOK 32.1 million, compared to NOK 34.3 million in the corresponding quarter of 2003.
- Net loss totalled NOK 16.2 million, compared to NOK 18.5 million in the first quarter of 2003.
- Liquid funds amounted to NOK 163.5 million as of 31 March 2004.

## **Sales of Metvix<sup>®</sup> continue to increase**

Sales of Metvix – PhotoCure’s product for treatment of skin cancer (basal cell carcinoma) and pre-cancerous skin lesions (actinic keratosis) – continued to increase and sales to pharmacies in the Nordic region increased by 53% compared to the corresponding quarter in 2003. In the Nordic region, a total of 272 light sources have now been installed at 176 clinics. Galderma’s sale of Metvix increased by 560% compared to the first quarter of 2003, and by 38% compared to fourth quarter of 2003. Total sales and milestone revenues for Metvix and light sources in all markets amounted to NOK 14.1 million, an increase of 36% over the revenues generated in the first quarter of 2003.

On the 7<sup>th</sup> May, PhotoCure is arranging a satellite symposium at the Nordic Congress for Dermatologists, at which highly ranked dermatologists will be presenting Metvix. Metvix presentations will also be held at several national medical congresses and meetings taking place in the Nordic countries during 2004.

## **Introducing Metvix to new markets**

Metvix is currently being marketed in the Nordic countries by PhotoCure and in Germany, UK and New Zealand by Galderma. Additionally, Galderma is planning to launch Metvix in Italy, Spain, Belgium, Australia and Switzerland during 2004. Metvix is currently approved for sales and marketing in 17 European countries as well as Australia and New Zealand. Further applications for marketing approval have already been submitted in the US, Czech Republic, Slovenia, South Africa, Brazil and Mexico, and in 2004 applications will be filed in Portugal, the Netherlands, Argentina, as well as in other countries that recently entered the EU.

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. The evaluation is in the final stage and PhotoCure is expecting a final approval in the second quarter of 2004. PhotoCure is entitled to receive Euro 3 million in milestone revenues from Galderma when Metvix gains marketing approval for actinic keratosis in the US.

In 2003, PhotoCure also applied for approval of Metvix for primary treatment of nodular basal cell carcinoma in the United States. This application was evaluated by the FDA which concluded that additional information was necessary in order to recommend approval of Metvix for this indication. PhotoCure continues to communicate with the FDA with the aim of obtaining approval for treatment of basal cell carcinoma, and is in the process of filing an amendment to the application.

## **Hexvix<sup>®</sup> approaching its launch**

The first marketing approval for Hexvix, PhotoCure’s product for the detection of urinary bladder cancer, is expected during 2004 from the Swedish Medicines Authorities. In order to obtain approval, a limited pharmacokinetic study has to be completed. Approval in Sweden will initiate the process for approvals from other EU/EEA countries. In the United States, a second clinical phase III study is currently underway as part of the preparation for the submission of a US marketing application.

Current standard methods for diagnosing bladder cancer (white light cystoscopy), allow a considerable number of early-stage tumours to remain undetected, which can lead to inadequate treatment with a high risk of the condition progressing. Bladder cancer is a dangerous illness with a high level of mortality if the cancer is allowed to develop without good, early stage treatment. 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, due to its fluorescence, be used to aid surgical removal of lesions.

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.

### **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. Results from the first phase III study are now published in the highly ranked Journal of Urology. In March, PhotoCure exhibited at the European Urology Association's annual congress in Vienna, and in May, Hexvix will be presented by opinion leaders at the American Urology Association's annual congress in the US. PhotoCure continues to evaluate potential partners for the sale and marketing of this product outside the Nordic region.

### **Intellectual property**

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 that were submitted, PhotoCure asserted that publications pre-dating 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 alleging that the sale of Metvix in Australia would infringe the patent no. 624985. A court hearing in the case took place in April this year and the ruling is expected during the second half of this year.

### **Financial position**

Operating revenues for the group amounted to NOK 15.4 million in the first quarter, compared to operating revenues of NOK 11.5 million in the same period of 2003. External R&D costs were significantly reduced in the first quarter compared to the corresponding quarter in 2003. The reduction in R&D costs were partly offset by an increase in other operating expenses due to higher litigation and marketing costs. In total, operating expenses decreased to NOK 32.1 million compared to NOK 34.3 million in the first quarter of 2003. Net loss amounted to NOK 16.2 million compared to NOK 18.5 in the first quarter of 2003.

Shareholders' equity for the group totalled NOK 115.9 million as of 31 March 2004 compared to NOK 131.9 million as of 31 December 2003. Liquid funds amounted to NOK 163.5 million as of 31 March 2004, compared to NOK 185.8 million as of 31 December 2003. An employee share issue of 5,704 shares were completed during first quarter of 2004, and the number of outstanding shares was 17,582,704 as of 31 March 2004.

The accounts for the quarter are based on the same accounting principles as stated in the annual report for 2003, and are in compliance with Norwegian GAAP requirements for quarterly reporting.

The Board of Directors of PhotoCure ASA

**Profit & Loss (Group)**  
(all amounts in NOK 1,000 except per share data)

<b>Three months ended</b>			<b>2003</b>
<b>31.03.04</b>	<b>31.03.03</b>		<b>01.01 - 31.12.</b>
14 087	10 425	Sales and milestone revenues	55 154
1 263	1 045	Other operating revenues	5 150
<b>15 350</b>	<b>11 470</b>	<b>Operating revenues</b>	<b>60 304</b>
3 999	3 830	Cost of products sold	9 514
8 077	7 343	Payroll expenses	27 757
6 478	14 219	External R&D	38 377
389	437	Ordinary depreciation	1 677
13 160	8 490	Other operating expenses	36 635
<b>32 102</b>	<b>34 318</b>	<b>Total operating expenses</b>	<b>113 959</b>
<b>-16 752</b>	<b>-22 848</b>	<b>Operating loss</b>	<b>-53 655</b>
1 389	4 969	Financial income	14 014
851	599	Financial expense	3 126
<b>538</b>	<b>4 370</b>	<b>Net financial income</b>	<b>10 888</b>
<b>-16 214</b>	<b>-18 478</b>	<b>Loss before tax</b>	<b>-42 767</b>
-	-	Tax expenses	-
<b>-16 214</b>	<b>-18 478</b>	<b>Net loss</b>	<b>-42 767</b>
-112	-72	Incl. minority interests in the amount of	-441
-0.92	-1.06	Net loss per share (1)	-2.44

(1) Calculation based on average weighted number of shares outstanding.

**Balance Sheet (all amounts in NOK 1,000)**

	<b>2004</b>	<b>2003</b>	<b>2003</b>
	<b>31.03</b>	<b>31.03</b>	<b>31.12</b>
Machinery & equipment	2,850	4,315	3,222
Financial fixed assets	8,013	7,850	7,832
<b>Total fixed assets</b>	<b>10,863</b>	<b>12,166</b>	<b>11,054</b>
<b>Current assets</b>			
Inventory	22,309	26,431	23,167
Receivables	16,337	17,208	13,335
Securities	147,336	197,687	170,309
Cash & cash equivalents	16,201	17,870	15,536
<b>Total current assets</b>	<b>202,183</b>	<b>259,195</b>	<b>222,348</b>
<b>Total assets</b>	<b>213,046</b>	<b>271,361</b>	<b>233,402</b>
Paid in capital	70,104	65,094	69,866
Retained earnings	45,818	83,628	62,031
<b>Shareholders' equity</b>	<b>115,922</b>	<b>148,722</b>	<b>131,897</b>
Long term liabilities	13,519	17,941	13,519
Current liabilities	83,606	104,698	87,985
<b>Total liabilities</b>	<b>97,125</b>	<b>122,639</b>	<b>101,504</b>
<b>Total equity and liabilities</b>	<b>213,046</b>	<b>271,361</b>	<b>233,402</b>

**Change in Equity (all amounts in NOK 1,000)**

	<b>Three months ended</b>		<b>2003</b>
	<b>31.03.04</b>	<b>31.03.03</b>	<b>01.01 - 31.12.</b>
<b>Equity at beginning of period</b>	<b>131,897</b>	<b>166,999</b>	<b>166,999</b>
Accrued subscription rights	41	201	-910
Share issue employees	197	-	5,883
Share increase in subsidiary	-	-	2,692
Net income/-loss for the period	-16,214	-18,478	-42,767
<b>Equity at end of period</b>	<b>115,922</b>	<b>148,722</b>	<b>131,897</b>

**Cash Flow Statement (all amounts in NOK 1,000)**

	<b>Three months ended</b>		<b>2003</b>
	<b>31.03.04</b>	<b>31.03.03</b>	<b>01.01 - 31.12.</b>
Loss before taxes	-16,214	-18,478	-42,767
Other operational items	-6,274	-15,458	-27,740
<b>Net cash flow from operations</b>	<b>-22,487</b>	<b>-33,936</b>	<b>-70,507</b>
Cash flow from investments	-17	-10	-1,426
Cash flow from capital transactions	197	0	8,275
<b>Net change in cash during the period</b>	<b>-22,308</b>	<b>-33,946</b>	<b>-63,658</b>
Cash & cash equivalents at beginning of period	185,845	249,503	249,503
<b>Cash &amp; cash equivalents at end of period</b>	<b>163,537</b>	<b>215,557</b>	<b>185,845</b>