

## **Increased revenues and reduced costs**

**PhotoCure ASA  
Second Quarter Report 2003**

### **Highlights:**

- **Net income of NOK 7.6 million in the 2<sup>nd</sup> quarter 2003 compared to a net loss of NOK 27.2 million in the 2<sup>nd</sup> quarter 2002. Operating revenues increased to NOK 25.3 million in the 2<sup>nd</sup> quarter, primarily due to milestone payment of NOK 16.1 million from Galderma compared to operating revenues of NOK 4.6 million in the same period of 2002. Operating expenses decreased to NOK 21.5 million compared to 34.0 million in the 2<sup>nd</sup> quarter of 2002. Liquid funds amounted to NOK 213.2 million as of 30 June 2003.**
- **Metvix<sup>®</sup> approved in Australia for the treatment of pre-cancerous skin disorder (actinic keratosis) and skin cancer (basal cell carcinoma).**
- **Positive Metvix<sup>®</sup> clinical results for immuno suppressed organ transplant patients – increased market potential.**
- **Collaboration agreement for Hexvix<sup>®</sup> signed with Karl Storz – important for marketing application in the US.**
- **Phase III trial results highlighting the clinical benefits of Hexvix<sup>®</sup> for detection of bladder cancer receives significant attention.**

The second quarter of 2003 has seen PhotoCure ASA continue to make significant progress towards its goal of being a pharmaceutical company with a profitable business in the field of cancer therapy and diagnosis.

### **First Quarterly Profit**

Due to milestone payments and fluctuating research and development costs, revenues and costs will vary significantly from quarter to quarter.

Sales revenues totalled NOK 25.3 million for the second quarter of 2003, compared to NOK 4.6 million in the same period of 2002. PhotoCure received and accounted for a milestone payment of Euro 2 million (NOK 16.1 million) in the second quarter 2003 as a result of the first commercial sales of Metvix<sup>®</sup> in Germany and the UK. Total operating expenses for the group amounted to NOK 21.5 million for the second quarter of 2003, compared to NOK 34.0 million during the same period of 2002. The decrease is primarily due to lower Metvix<sup>®</sup> and Hexvix<sup>®</sup> development costs. Net income for the group totalled NOK 7.6 million for the three months ending 30 June 2003, compared to a net loss of NOK 27.2 million in the same period in 2002.

Shareholders' equity totalled NOK 161.7 million as of 30 June 2003 compared to NOK 167.0 million as of 31 December 2002. Liquid funds amounted to NOK 213.2 million as of 30 June 2003, compared to NOK 215.6 million as of 31 March 2003. The funds are mainly invested in money market funds. The number of outstanding shares was 17,505,000 as of 30 June 2003.

### **European Roll Out of Metvix<sup>®</sup> Continues**

Metvix<sup>®</sup>, PhotoCure's novel photodynamic therapy product for the treatment of pre-cancerous skin disorder (actinic keratosis) and skin cancer (basal cell carcinoma, the most common type of skin cancer), has already been introduced in Norway, Sweden, Finland, Denmark, Germany and the UK. It is approved for marketing in most European countries, New Zealand and Australia, and it has been deemed approvable for pre-cancerous skin disorder in the US.

In May 2003, Galderma hosted a launch symposium for selected opinion leaders in the UK for Metvix<sup>®</sup>. Galderma is PhotoCure's global marketing partner for Metvix<sup>®</sup> outside of the Nordic countries. The symposium was held in Seville, as part of the 2003 World Congress on Cancers of the Skin. At the Congress, Galderma also hosted a satellite symposium for the Metvix<sup>®</sup> treatment with almost 300 participants. Galderma has established several educational centres in the UK to ensure solid training for clinicians who wish to start practising the treatment. Galderma introduced Metvix<sup>®</sup> in Germany in February 2003 and is pleased with the clinical acceptance that Metvix<sup>®</sup> has received in Germany and the UK.

The marketing of Metvix<sup>®</sup> in the Nordic countries has reached a solid basis for future sales growth as the acceptance among dermatologists is high, with more than 220 light sources installed at close to 150 clinical centres. Drug reimbursement is established in Sweden, Norway, Finland and to some extent in Denmark. Reimbursement of the Metvix<sup>®</sup> treatment procedure for dermatologist with a private practice is now in place in Norway and in certain regions in Denmark.

## **Expanding the Commercial Potential of Metvix<sup>®</sup>**

Looking ahead, PhotoCure is confident that the sales of Metvix<sup>®</sup> will continue to increase. This optimism is based on a number of recent important events:

- The regulatory approval in Australia for the treatment of pre-cancerous skin disorder (AK) and skin cancer (BCC). With the highest frequency of sun-induced skin diseases in the world, Australia constitutes a large market opportunity for Metvix<sup>®</sup>;
- The US Food and Drug Administration (FDA) evaluation of the New Drug Application submitted for Metvix<sup>®</sup> for the treatment of skin cancer (BCC) progresses as an advisory committee meeting will be held on 10 September 2003. Metvix<sup>®</sup> is already deemed 'approvable' for treatment of pre-cancerous skin disorder (AK);
- Positive new clinical results with Metvix<sup>®</sup> in the treatment of patients with early squamous cell carcinoma (SCC). SCC is a more aggressive non-melanoma skin cancer than basal cell carcinoma, and the Metvix<sup>®</sup> treatment shows superiority compared to alternative treatments;
- A clinical study with Metvix<sup>®</sup> on immunosuppressed organ transplant patients shows 90% lesion response for pre cancerous skin lesions. This constitutes a large market opportunity for Metvix<sup>®</sup>.

## **Hexvix<sup>®</sup> for Detection of Bladder Cancer Closer to Commercialisation**

Through a collaboration agreement PhotoCure and Karl Storz GmbH (Tuttlingen, Germany) have agreed to apply for a combined marketing approval in the US for Hexvix<sup>®</sup> and Karl Storz' D-light system for detection of bladder cancer. Karl Storz' D-light system is already approved in Europe. Karl Storz is a leading manufacturer of advanced endoscopes, instruments and equipment for use in minimal invasive surgery, including urology. The company has a worldwide presence and has introduced several innovative products around the world over the past 50 years.

As a result of a previous collaboration, PhotoCure conducted clinical trials in 28 leading urology clinics in Europe with both the D-light system and Hexvix<sup>®</sup>. This enabled PhotoCure to complete the European regulatory application for Hexvix<sup>®</sup>. A comprehensive program is now ongoing in the USA and Canada, including 19 leading urology clinics. The application for marketing approval in the USA for Hexvix<sup>®</sup> and the D-light system will be submitted next year.

As a part of the pre-launch activities for the introduction of Hexvix<sup>®</sup> detection of bladder cancer on the Nordic markets, PhotoCure organised a satellite symposium at the Scandinavian congress for urologists, which was recently held in Bergen, Norway. The speakers at the symposium were all internationally highly recognized clinicians and scientists who have participated in the development of Hexvix<sup>®</sup>. At this symposium, clinical data from the two completed European phase III multi-centre trials were presented. These data highlighted that significantly more (30%) cancers (carcinoma in situ) are detected with Hexvix<sup>®</sup> compared to standard white light cystoscopy, and that Hexvix<sup>®</sup> will be an important tool for improved detection of bladder cancer. In addition, the trials show that Hexvix<sup>®</sup> would lead to important changes in patient management, with clear benefits for the prognosis of patients.

PhotoCure's first Marketing Authorisation Application (MAA) for Hexvix<sup>®</sup> was filed in Sweden in December 2002 as the first step in gaining pan European approval for this promising new product.

#### Profit & Loss (Group)

(all amounts in NOK 1,000 except per share data)

Three months ended			Six months ended		2002
30.06.03	30.06.02		30.06.03	30.06.02	01.01 - 31.12
24,285	4,594	Sales revenues	34,710	8,291	25,222
1,045	6	Other operating revenues	2,090	130	3,486
<b>25,330</b>	<b>4,601</b>	<b>Operating revenues</b>	<b>36,800</b>	<b>8,422</b>	<b>28,708</b>
1,634	536	Cost of products sold	5,464	606	5,832
5,383	1,028	Payroll expenses	12,725	4,874	18,796
4,299	21,821	External R&D	18,518	45,356	77,300
423	312	Ordinary depreciation	860	545	1,269
9,739	10,348	Other operating expenses	18,229	19,249	35,039
<b>21,478</b>	<b>34,045</b>	<b>Total operating expenses</b>	<b>55,796</b>	<b>70,630</b>	<b>138,235</b>
<b>3,852</b>	<b>-29,444</b>	<b>Operating income/-loss</b>	<b>-18,996</b>	<b>-62,208</b>	<b>-109,527</b>
4,625	5,411	Financial income	9,594	10,447	20,271
915	3,136	Financial expense	1,514	4,918	6,750
<b>3,710</b>	<b>2,275</b>	<b>Net financial income</b>	<b>8,080</b>	<b>5,529</b>	<b>13,521</b>
<b>7,561</b>	<b>-27,169</b>	<b>Income/-loss before tax</b>	<b>-10,917</b>	<b>-56,678</b>	<b>-96,006</b>
-	-	Tax expenses	-	-	-
<b>7,561</b>	<b>-27,169</b>	<b>Net income/-loss</b>	<b>-10,917</b>	<b>-56,678</b>	<b>-96,006</b>
-157	-235	Minority interests	-230	-548	-906
0.43	-1.56	Earnings/ net loss per share (1)	-0.63	-3.26	-5.51

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

#### Balance Sheet (Group)

(all amounts in NOK 1,000)

	2003	2002	2002
	30.06	30.06	31.12
Fixed assets	11,815	11,413	12,421
Inventory	26,147	19,400	26,132
Receivables	16,734	4,781	10,950
Securities	181,949	221,229	215,414
Cash & cash equivalents	31,278	83,930	34,089
<b>Total assets</b>	<b>267,924</b>	<b>340,752</b>	<b>299,006</b>
Shareholders' equity	161,651	206,212	166,999
Long term liabilities	17,661	17,524	17,879
Current liabilities	88,612	117,016	114,127
<b>Total equity and liabilities</b>	<b>267,924</b>	<b>340,752</b>	<b>299,006</b>

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

	Six months ended		2002
	30.06.03	30.06.02	01.01-31.12
<b>Equity at beginning of period</b>	<b>166,999</b>	<b>259,398</b>	<b>259,398</b>
Accrued subscription rights	401	272	-273
Share issue employees	2,475	3,220	3,897
Share increase in subsidiary	2,692	-	1
Purchase of shares from minority		-	-19
Net loss for the period	-10,917	-56,678	-96,006
<b>Equity at end of period</b>	<b>161,651</b>	<b>206,212</b>	<b>166,999</b>

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

	Six months ended		2002
	30.06.03	30.06.02	01.01-31.12
Loss before taxes	-10,917	-56,678	-96,006
Other operational items	-30,425	61,330	45,100
<b>Net cash flow from operations</b>	<b>-41,341</b>	<b>4,652</b>	<b>-50,906</b>
Net cash flow from investing activities	-101	-8,022	-8,906
Net cash flow from capital transactions	5,167	3,350	4,137
<b>Net change in cash &amp; cash equivalents</b>	<b>-36,276</b>	<b>-20</b>	<b>-55,675</b>
Cash & cash equivalents at beginning of period	249,503	305,178	305,178
<b>Cash &amp; cash equivalents at end of period</b>	<b>213,227</b>	<b>305,158</b>	<b>249,503</b>

The Board of Directors of PhotoCure ASA