

## **PhotoCure ASA – Commercialisation of Metvix<sup>®</sup> PDT in Europe on track**

### **Highlights 1<sup>st</sup> quarter 2002**

#### ***Commercialisation of Metvix<sup>®</sup> PDT***

- *The Metvix<sup>®</sup> PDT approval is recognised by 14 European countries and national marketing authorisations are now issued in Sweden, Norway, Denmark, Iceland, Germany, United Kingdom, Ireland, Luxembourg and New Zealand. In the 6 remaining countries, PhotoCure is awaiting the final approval.*
- *Commercialisation of Metvix<sup>®</sup> PDT in the Nordic countries is on track.*
- *Galderma, PhotoCure's exclusive marketing partner for Metvix<sup>®</sup> PDT, prepares for its launch in major pharmaceutical markets outside the Nordic region.*
- *Marketing authorisation application is pending in the US.*
- *Additional Phase III results strengthen claims for Metvix<sup>®</sup> PDT*

#### ***Hexvix<sup>®</sup> in Phase III Clinical Trials***

- *Hexvix<sup>®</sup> fluorescence cystoscopy to detect bladder cancer has now entered clinical Phase III trials in the US and Europe.*
- *The first results from these studies are expected during the 2<sup>nd</sup> half of 2002.*

#### ***Benzvix<sup>®</sup> in Early Studies for New Indications***

- *Benzvix<sup>®</sup> is being developed as a product for photodiagnostics and photodynamic therapy (PDT) for lesions in the gastro-intestinal tract. Pilot studies on patients with pre-malignant lesions in the oesophagus and colon have been initiated.*

#### ***Financial position***

- *Total expenses of NOK 36.6 million and a net loss of NOK 29.5 million for the three months ending 31 March 2002 were as expected. Liquid funds totalled NOK 358.2 million as of 31 March 2002.*

## **Metvix<sup>®</sup>PDT Commercialisation Progresses**

Commercialisation of Metvix<sup>®</sup>PDT for the treatment of actinic keratosis (AK) and basal cell carcinoma (BCC) continues to progress as planned. Metvix<sup>®</sup>PDT has been launched in Sweden and market introduction activities are ongoing in Norway and Denmark. In Sweden, 46 centres have participated in PhotoCure's educational courses and 32 additional centres are about to be trained. Moreover, a total of 60 light sources have been placed at 41 different centres in Sweden.

During the 1<sup>st</sup> quarter of 2002, PhotoCure received marketing authorisation for Metvix<sup>®</sup>PDT from the individual regulatory authorities in Norway, Denmark, Iceland, Germany, United Kingdom, Ireland and Luxembourg, to add to that already received from Sweden. The company also was granted marketing authorisation in New Zealand, the first outside of Europe. An additional filing for approval was submitted to the Swiss authorities in January. Australian Authorities are requesting additional clinical data to approve the marketing authorisation application. PhotoCure will submit additional clinical data for AK and BCC from studies that are already completed to the Australian Authorities. A marketing authorisation application is also pending in the US.

Galderma, PhotoCure's exclusive marketing partner for Metvix<sup>®</sup>PDT is preparing to launch Metvix<sup>®</sup>PDT in the major pharmaceutical markets outside the Nordic region, including the rest of Europe and New Zealand.

## **Additional Phase III Results Strengthen Claims for Metvix<sup>®</sup>PDT**

PhotoCure has performed additional Phase III trials in Europe to reinforce the claims for Metvix<sup>®</sup>PDT as a treatment with a high cure rate and few or none side effects. The first results from two five-year trials involving more than 200 BCC patients, were announced in February, at the end of the first 12-month period of the trials.

These trials were designed to show two things: first, to demonstrate that Metvix<sup>®</sup>PDT is as effective as existing treatments for BCC (surgery or cryotherapy) in terms of the disease recurrence rates and second, that the cosmetic outcomes of treatment with Metvix<sup>®</sup>PDT are significantly better than with standard treatment. The cosmetic outcome is important for patients with BCC on cosmetically sensitive areas, particularly the face.

At the 12-month stage, for superficial BCC lesions, there was an 8% recurrence rate with Metvix<sup>®</sup>PDT compared to 16% recurrence rate for cryotherapy, whereas, for nodular BCC lesions, there was a 4% recurrence rate for Metvix<sup>®</sup>PDT compared to 0% for surgery. At the same time, the dermatologists graded the cosmetic outcome as 'good' or 'excellent' in 80% of the Metvix<sup>®</sup>PDT patients with nodular BCC compared to only 38% who had had surgery. In patients with superficial BCC, 89% of the Metvix<sup>®</sup>PDT patients were graded 'good' or 'excellent' compared to 62% of patients who had had cryotherapy treatment.

These results will confirm those provided to the regulatory authorities still considering the previously submitted marketing applications, thereby strengthening the overall submission package.

### **Hexvix<sup>®</sup> Phase III Trials program ongoing**

Patient enrolment has now been completed in the first Phase III study. This study includes around 250 patients in 22 leading university hospitals across Europe and is designed to document the safety and efficacy of Hexvix<sup>®</sup> fluorescence cystoscopy for the detection of bladder cancer. Another Phase III study has also been initiated in Europe. Phase III trials have also been initiated in 17 leading urology centres in the US following the US Food and Drug Administration's (FDA) approval of PhotoCure's Investigational New Drug (IND) application for Hexvix<sup>®</sup>.

The first results from these international studies are expected in the second half of 2002, and the first filing for marketing approval is expected during the first half of 2003. In Phase II trials, Hexvix<sup>®</sup> detected four times as many patients with serious malignant tumours than standard cystoscopy. Bladder cancer is the sixth most malignant disease worldwide, and every year more than 2.5 million cystoscopies (bladder inspections) are performed in Europe and North America in order to diagnose or rule-out bladder cancer. The main problem with conventional cystoscopy is that a significant number of early cancers cannot be accurately detected and hence the recurrence rate after treatment is reported to be as high as 70%.

Patients with these recurrent tumours also have a high risk of progression (30%) and this often necessitates the surgical removal of the entire bladder. Earlier and more accurate detection of these tumours will therefore contribute to improved patient management and outcomes. The commercial potential for Hexvix<sup>®</sup> fluorescence cystoscopy is therefore substantial.

### **PCI Biotech AS**

PCI Biotech continues to focus its business on the opportunities for photochemical internalisation (PCI) as a platform technology in drug discovery, development and delivery of novel cancer therapeutics.

Pilot studies in cancer patients are planned to be initiated during 2003. The commercial potential within cancer treatment is significant. PCI Biotech is currently developing a proprietary photosensitiser, clinically optimised and specially designed for PCI. PCI Biotech AS products for the research market, LumiSource<sup>®</sup> and LumiTrans<sup>®</sup> will be offered to potential licensing partners who have already established a strong position on this market.

### **Strong Equity and Cash Position**

Total operating expenses for the group amounted to NOK 36.6 million for the three months ending 31<sup>st</sup> of March 2002 compared to NOK 22.6 million during the same period of 2001. The increase is associated with product development activities as well as marketing activities related to Metvix<sup>®</sup> PDT. Net loss for the group totalled NOK

29.5 million for the three months ending 31<sup>st</sup> of March 2002 compared to NOK 14.4 million in the same period in 2001.

Shareholders equity totalled NOK 233.1 million as of 31<sup>st</sup> of March 2002 compared to NOK 259.4 as of 31<sup>st</sup> of December 2001. Total liquidity amounted to NOK 358.2 million as of 31<sup>st</sup> of March 2002 and is mainly invested in money market funds. The number of outstanding shares was 17,420,000 as of 30<sup>th</sup> of March 2002.

**Profit & Loss (Group)**

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

Three month ended			2001
31.03.02	31.03.01		1.1-31.12
3 697	402	Sales	2 330
124	625	Other operating revenues	3 022
<b>3 821</b>	<b>1 027</b>	<b>Operating revenues</b>	<b>5 352</b>
3 845	5 095	Salaries & other pers. costs	25 737
23 536	12 820	External R&D	78 036
232	159	Ordinary depreciation	758
8 971	4 494	Other operating costs	28 687
<b>36 584</b>	<b>22 568</b>	<b>Total operating expenses</b>	<b>133 218</b>
<b>-32 763</b>	<b>-21 541</b>	<b>Operating loss</b>	<b>-127 866</b>
<b>3 253</b>	<b>7 097</b>	<b>Net financial income</b>	<b>26 178</b>
<b>-29 510</b>	<b>-14 443</b>	<b>Loss before tax</b>	<b>-101 688</b>
0	0	Taxes	0
<b>-29 510</b>	<b>-14 443</b>	<b>Net loss</b>	<b>-101 688</b>
-313	6	Minority interests	-1 074
-1.70	-0.84	Net loss per share (1)	-5.93

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

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

	2002	2001
	31.03	31.12
Fixed assets	4 075	3 935
Receivables	18 445	10 456
Securities	241 556	283 564
Cash & cash equivalents	116 640	21 614
<b>Total assets</b>	<b>380 716</b>	<b>319 569</b>
Shareholders' equity	233 108	259 398
Long term liabilities	17 447	17 362
Current liabilities	130 161	42 809
<b>Total equity and liabilities</b>	<b>380 716</b>	<b>319 569</b>

**The Board of Directors of PhotoCure ASA**