



## Second Quarter Report 2004

### Metvix Approved in the US

#### Highlights

- Metvix<sup>®</sup> approved in the US for the treatment of actinic keratosis.
- Metvix launches initiated in Australia, Belgium and Switzerland by Galderma.
- The number of Metvix units sold to pharmacies in the Nordic region increased by 66% compared to the corresponding quarter in 2003.
- Hexvix<sup>®</sup> - A pharmacokinetic study required for approval in Sweden for this product was successfully completed in June 2004.
- Sales revenues increased to NOK 9.6 million in the second quarter 2004, compared to NOK 4.2 million in the corresponding quarter in 2003.
- Net loss totalled NOK 15.1 million, compared to a profit of NOK 7.6 million in the second quarter of 2003. Adjusted for a one-off milestone payment, net loss totalled 8.5 million in the second quarter of 2003. Liquid funds amounted to NOK 144.8 million as of 30 June 2004.

## **Metvix<sup>®</sup> Approved in the US**

On the 27<sup>th</sup> of July, the U.S. Food and Drug Administration (FDA) approved methyl aminolevulinate (Metvix) and CureLight for treatment of actinic keratosis. Due to the similarity of the Metvix trade name to an already existing dermatology product in the US, this is contingent on the FDA's acceptance of a trade name other than Metvix. PhotoCure has already applied for another tradename, and a response from the FDA is expected within weeks. As a result of the approval, PhotoCure will receive a milestone payment of EUR 3 million from Galderma.

PhotoCure remains in continued discussions with the FDA in order to obtain approval for Metvix for the treatment of basal cell carcinoma. Following the 'non approvable' FDA evaluation in 2003 and subsequent communication with the FDA, an amendment to the NDA was submitted in June and a response is expected from the FDA by the end of 2004.

Metvix was approved in Hungary and Slovenia during the quarter and is currently approved for sales and marketing in 18 European countries as well as in the US, Australia and New Zealand. Applications are pending in 11 additional countries, 8 of which are European.

## **Metvix<sup>®</sup> Sales Increases**

Sales of Metvix continued to increase in the Nordic area, where sales to pharmacies totalled 2596 units in the second quarter, an increase of 66% compared to the corresponding quarter in 2003. Galderma, responsible for marketing and sales outside of the Nordic area, sold 2855 units of Metvix in the second quarter of 2004, compared to 773 units in the second quarter of 2003. Total sales revenues for Metvix on all markets amounted to NOK 9.6 million, compared to NOK 4.2 million in the second quarter in 2003.

The number of clinical centres offering Metvix treatment continues to expand and a total of 279 light sources have now been installed at 181 clinics. Galderma has now initiated launches of Metvix in Australia, Belgium and Switzerland, extending the actively marketed territories to six countries in addition to the Nordic area covered by PhotoCure. Metvix is now also made available in Italy, and launch in Spain is planned later in 2004.

## **Hexvix<sup>®</sup> Closer to Approval and Commercialisation**

Following a prior request from the Swedish Medicines Authority, a pharmacokinetic study with Hexvix was successfully completed and submitted in June 2004. Based on this data submission and previous communication with the authorities, PhotoCure expects that Hexvix will receive marketing approval from the Swedish Medicines Authorities for the detection of urinary bladder cancer before the end of 2004. Approval in Sweden will pave the way for approvals from other EU/EEA countries via the mutual recognition procedure.

PhotoCure has scheduled a meeting with the FDA to discuss the possibility to apply for marketing approval in the US based on data from the European filing.

PhotoCure is conducting health economy research for Hexvix. Preparations for launch are ongoing and PhotoCure continues to evaluate potential partners for the sale and marketing of this product.

## **R&D Pipeline**

PhotoCure has together with key dermatologist in Europe performed a clinical pilot project to assess the possible usefulness of Metvix for treatment of acne. Based on positive results, PhotoCure together with Galderma have initiated a single center dose-response study with Metvix in acne and an additional clinical efficacy study in inflammatory acne are planned to be initiated at several centers in Europe. The global pharmaceutical market for moderate to severe acne today is approximately 1 billion USD. Together with Galderma, PhotoCure is also conducting a study in organ transplant patients, in order to assess the usefulness of Metvix in treating the dermatological disorders these patients experience.

PhotoCure has performed preclinical work including pharmaceutical formulation for use in detection of colon cancer. An explorative study using hexaminolevulinate was performed in 10 patients with colorectal cancer and showed good tolerability as well as indicating the preferential uptake of photoactive porphyrins in cancerous tissue. Based on these positive findings, PhotoCure will initiate further clinical work in this indication. PhotoCure is also evaluating further clinical studies in in gynaecology following positive initial data in this indication.

## **PCI Biotech**

PCI Biotech AS, a subsidiary of PhotoCure, is developing Photochemical Internalisation (PCI), a proprietary, light-induced, drug delivery technology. The company conducts research in collaboration with companies and internationally recognised academic research centers. As a result of this, the technology has in animal models significantly increased the efficiency of anti-cancer cytotoxic substances and cancer gene therapy. Progress is also made in optimisation of a proprietary photosensitiser for use as part of the technology.

## **Intellectual property**

PhotoCure is awaiting a judgment later this year following a hearing in the Federal Court of Australia in April 2004. The court hearing followed on an Australian patent suit relating to PhotoCure's filing for invalidation of a patent assigned to Queen's University in Kingston, Canada. This patent relates to the use of photodynamic therapy using 5-aminolevulinic acid and is licensed to DUSA Pharmaceuticals, Inc. DUSA filed a cross-claim in the same proceeding alleging that the sale of Metvix in Australia would infringe the patent.

On 17 August 2004, DUSA, Queens University, Galderma and PhotoCure entered into a Mediation agreement designed to facilitate resolution of the parties' potential patent disputes.

## **Financial position**

Operating revenues for the group amounted to NOK 14.7 million in the second quarter, compared to operating revenues of NOK 25.3 million in the same period of 2003. Operating revenues in the second quarter of 2003 included NOK 16.1 million in milestone payment from Galderma.

Operating expenses increased to NOK 26.7 million compared to NOK 19.8 million in the second quarter of 2003. The increase was due to higher research and development costs, as the corresponding costs in the second quarter of 2003 were exceptionally low. In addition, the increase

was due to higher patent litigation costs as well as higher marketing costs. Net loss amounted to NOK 15.1 million compared to a profit of NOK 7.6 in the second quarter of 2003.

Shareholders' equity for the group totalled NOK 100.9 million as of 30 June 2004 compared to NOK 131.9 million as of 31 December 2003. Liquid funds amounted to NOK 144.8 million as of 30 June 2004 (this amount does not include the forthcoming EUR 3 million milestone payment), compared to NOK 185.8 million as of 31 December 2003. The number of outstanding shares was 17,582,704 as of 30 June 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.

19<sup>th</sup> of August 2004  
The Board of Directors of PhotoCure ASA

**Profit & Loss (Group)**

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

Three months ended			2004	2003	2003
30.06.04	30.06.03		01.01 - 30.06.	01.01 - 30.06.	01.01 - 31.12.
9 607	4 236	Sales revenues	19 786	10 753	23 380
3 908	20 048	Signing fee and milestone revenues	7 817	23 957	31 774
1 182	1 045	Other operating revenues	2 445	2 090	5 150
<b>14 698</b>	<b>25 330</b>	<b>Operating revenues</b>	<b>30 048</b>	<b>36 800</b>	<b>60 304</b>
<b>4 085</b>	<b>1 634</b>	<b>Cost of products sold</b>	<b>8 083</b>	<b>5 464</b>	<b>9 514</b>
<b>10 613</b>	<b>23 696</b>	<b>Gross profit</b>	<b>21 965</b>	<b>31 336</b>	<b>50 790</b>
5 624	5 383	Payroll expenses	13 702	12 725	27 757
7 655	4 299	External R&D	14 132	18 518	38 377
377	423	Ordinary depreciation	766	860	1 677
13 009	9 739	Other operating expenses	26 168	18 229	36 635
<b>26 665</b>	<b>19 844</b>	<b>Total operating expenses</b>	<b>54 768</b>	<b>50 332</b>	<b>104 446</b>
<b>-16 051</b>	<b>3 852</b>	<b>Operating income/-loss</b>	<b>-32 803</b>	<b>-18 996</b>	<b>-53 655</b>
1 302	4 625	Financial income	2 691	9 594	14 014
347	915	Financial expense	1 197	1 514	3 126
<b>956</b>	<b>3 710</b>	<b>Net financial income</b>	<b>1 494</b>	<b>8 080</b>	<b>10 888</b>
<b>-15 096</b>	<b>7 561</b>	<b>Income/-loss before tax</b>	<b>-31 309</b>	<b>-10 917</b>	<b>-42 767</b>
-	-	Tax expenses	-	-	-
<b>-15 096</b>	<b>7 561</b>	<b>Net income/-loss</b>	<b>-31 309</b>	<b>-10 917</b>	<b>-42 767</b>
-52	-157	Incl. minority interests in the amount of	-164	-230	-441
-0.86	0.43	Net loss per share (1)	-1.78	-0.63	-2.44

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

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

	2004	2003	2003
	30.06	30.06	31.12
Machinery & equipment	2,474	3,965	3,222
Financial fixed assets	8,013	7,850	7,832
<b>Total fixed assets</b>	<b>10,486</b>	<b>11,815</b>	<b>11,054</b>
<b>Current assets</b>			
Inventory	20,251	26,147	23,167
Receivables	15,344	16,734	13,335
Securities	129,000	181,949	170,309
Cash & cash equivalents	15,819	31,278	15,536
<b>Total current assets</b>	<b>180,414</b>	<b>256,108</b>	<b>222,348</b>
<b>Total assets</b>	<b>190,900</b>	<b>267,924</b>	<b>233,402</b>
Paid in capital	70,145	67,770	69,866
Retained earnings	30,722	93,881	62,031
<b>Shareholders' equity</b>	<b>100,867</b>	<b>161,651</b>	<b>131,897</b>
Long term liabilities	13,519	17,661	13,519
Current liabilities	76,514	88,612	87,985
<b>Total liabilities</b>	<b>90,033</b>	<b>106,273</b>	<b>101,504</b>
<b>Total equity and liabilities</b>	<b>190,900</b>	<b>267,924</b>	<b>233,402</b>

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

	Six months ended		2003
	30.06.04	30.06.03	01.01 - 31.12.
<b>Equity at beginning of period</b>	<b>131,897</b>	<b>166,999</b>	<b>166,999</b>
Accrued subscription rights	83	401	-910
Share issue employees	197	2,475	5,883
Share increase in subsidiary	-	2,692	2,692
Net income/-loss for the period	-31,309	-10,917	-42,767
<b>Equity at end of period</b>	<b>100,867</b>	<b>161,651</b>	<b>131,897</b>

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

	Six months ended		2003
	30.06.04	30.06.03	01.01 - 31.12.
Loss before taxes	-31,309	-10,917	-42,767
Other operational items	-9,896	-30,425	-27,740
<b>Net cash flow from operations</b>	<b>-41,205</b>	<b>-41,341</b>	<b>-70,507</b>
Cash flow from investments	-17	-101	-1,426
Cash flow from capital transactions	197	5,167	8,275
<b>Net change in cash during the period</b>	<b>-41,026</b>	<b>-36,276</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>144,819</b>	<b>213,227</b>	<b>185,845</b>