



## Third Quarter Report 2006

### Highlights

- **GE Healthcare exercised an option to market and distribute Hexvix® in the US. This triggered a milestone payment of EUR 9 million to be booked in fourth quarter.**
- **Hexvix launched in Germany by GE Healthcare.**
- **Metvix® launched in Brazil. Metvixia® approved for AK, BCC and Bowen's in France.**
- **First Phase II study in acne completed.**
- **First clinical study for treatment of Cervix cancer started.**
- **Sales revenues in third quarter amounted to NOK 14.6 million (7.3), an increase of 99%.**
- **Net loss third quarter amounted to NOK -11.8 million (-4.8) due to higher R&D expenses.**
- **Cash amounted to NOK 271.5 million (81.0) at the end of the period.**

### GE Healthcare exercised the US option for Hexvix

GE Healthcare exercised the option to market and distribute Hexvix in the US market in July. The agreement was approved by the US authorities on October 18<sup>th</sup>, 2006 and Photocure will receive a milestone payment of EUR 9 million related to the option in the fourth quarter 2006.

### Hexvix - regulatory and market update

Hexvix is an innovative and effective diagnostic method for all types of bladder cancer. The results are particularly good for *Carcinoma In Situ* (CIS) lesions, which are difficult to detect with white light cystoscopy. Hexvix, which is an adjunct procedure to standard cystoscopy, improves the overall tumour detection by introducing tumour fluorescence.

Photocure and GE Healthcare are working on the introduction of Hexvix. Hexvix was launched in Germany in September.

Photocure has received a letter from the United States Food and Drug Administration (FDA) related to the Hexvix application (NDA). The FDA has requested additional analyses and information. Photocure is, together with its regulatory advisors and its licensing partner, discussing the requests with the FDA in order to agree on a plan to solve outstanding issues. The NDA is open and will be complemented with the additional requirements to be agreed upon with FDA.

### Metvix gaining momentum

Galderma sold 7,521 units outside the Nordic countries in the third quarter of 2006 compared to 5,738 units in the corresponding quarter of 2005, an increase of 31%. Galderma sold 24,873 Metvix units in the first three quarters of 2006, an increase of 47% above 2005.



Photocure sold 2,624 units to pharmacies in the Nordic countries in the third quarter of 2006 compared to 2,756 units in the corresponding quarter of 2005, a decrease of 5%. Metvix and Aktelite sales revenue in the third quarter increased, however, with 37% compared with third quarter 2005. Photocure sold 10,432 Metvix units in the first three quarters of 2006, an increase of 15% above 2005.

Galderma launched Metvix in Brazil in September. Metvixia was approved for AK, BCC and Bowen's in France in third quarter 2006.

Results of a recently finished phase III study in organ transplant recipients with cancerous and precancerous skin conditions was presented at the 15<sup>th</sup> EADV congress in Greece. The multicenter study included 81 patients from 11 centers in 5 European countries. The results showed that the development of new precancerous lesions was reduced by treatment of Metvix PDT compared to conventional patient management.

Non-melanoma skin cancers are more frequent and more aggressive in organ transplant recipients due to immuno-suppression. These lesions cause high morbidity and mortality in these patients. There is a great need for new treatment with less scarring and disfiguration. In addition, there is a great medical need for treatments that can eliminate sub-clinical disease and prevent the development of more serious skin cancer lesions in these high risk patients. The market for Metvix in these patients is estimated to be similar in volume to the BCC market for Metvix.

#### **Progress in clinical development programs**

Photocure has a portfolio of four internal R&D projects. All projects have made good progress in the third quarter:

##### ***Acne – treatment of moderate to severe inflammatory acne***

The acne project targets development of a novel treatment for moderate to severe acne based on Photocure's patented PDT technology. The first phase I/IIa study for dose selection was completed in third quarter 2006. The study gave valuable information on dose and time from application of cream to illumination in inflammatory acne. The next phase II study is a confirmatory dose finding study and is planned to start late 2006 at ten centres in the US.

##### ***Cervix – treatment of cervix cancer***

The cervix project targets treatment of precancerous-/cancer lesions in cervix. Photocure started the first clinical study in September 2006. This study is designed as a phase II study and will include 70-80 patients at two centres in Oslo, Norway and Hannover, Germany.

##### ***Colon – diagnosis of colon cancer***

The colon project targets development of an optical agent for diagnosis of colon cancer. It builds on Photocure's extensive knowledge of early detection of bladder cancer. The first patients were enrolled in a clinical study in June. This dose finding study will include up to 30 patients and be conducted in Germany. The objective is to investigate if fluorescence from an optical agent with the use of blue light colonoscopy can detect more cancers than the traditional method used today.

##### ***PCI Biotech AS – enhancement and site-direction of cancer therapy***

PCI is a patented technology that can be used to enhance the effect of drugs by targeted illumination of the diseased areas of the body. The main goal is to develop a proprietary photosensitiser for enhancement and site-direction of therapy with anticancer agents. A reproducible synthesis protocol



for the photosensitiser has been established and preparation for the first clinical study is ongoing. The study is planned to start in 2007.

PCI Biotech was granted a NOK 5.4 million research grant over the next 3 years from the Norwegian Research Foundation in September.

### **Financial position**

Sales, signing fee and milestone revenues totalled NOK 18.5 million for the quarter, compared to NOK 11.2 million in the third quarter of 2005. Sales revenues were NOK 14.6 million in the third quarter, compared to NOK 7.3 million in the third quarter of 2005, an increase of 99 %. The sales increase is mainly due to higher sales outside the Nordic region.

Operating expenses, including other operating revenues, amounted to NOK 28.1 million, compared to NOK 19.2 million in the third quarter of 2005. The increase is mainly due to higher R&D expenses.

Net loss amounted to NOK -11.8 million compared to a net loss of NOK -4.8 million in the third quarter of 2005.

Total equity for the group totalled NOK 271.0 million at the end of September 2006 compared to NOK 48.5 million at the end of 2005. Liquid funds amounted to NOK 271.5 million at the end of September 2006, compared to NOK 72.3 million at the end of December 2005. The number of outstanding shares was 22,034,972 at the end of September 2006.

The accounting policies adopted in this report are consistent with those followed in the preparation of the Group's annual financial statements for 2005 and complies with IFRS and IAS 34.

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26 October 2006  
The Board of Directors of Photocure ASA



**PhotoCure**

**Profit & Loss (Group)**

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

Three months ended			2006	2005	2005
30.09.2006	30.09.2005		01.01 - 30.09	01.01 - 30.09	01.01 - 31.12
14 575	7 322	Sales revenues	39 513	24 994	38 007
3 908	3 908	Signing fee and milestone revenues	72 290	11 725	15 634
<b>18 483</b>	<b>11 230</b>	<b>Sales, signing fee and milestone revenues</b>	<b>111 803</b>	<b>36 720</b>	<b>53 641</b>
-4 053	-2 392	Cost of products sold	-11 462	-9 896	-13 430
<b>14 431</b>	<b>8 839</b>	<b>Gross profit</b>	<b>100 341</b>	<b>26 824</b>	<b>40 211</b>
1 617	1 870	Other operating revenues	4 558	14 203	15 235
-9 049	-9 469	Payroll expenses	-23 216	-23 412	-29 369
-12 264	-6 074	External R&D expenses	-26 910	-28 630	-38 238
-335	-209	Ordinary depreciation	-875	-901	-1 125
-8 066	-5 310	Other operating expenses	-27 588	-21 575	-33 966
<b>-13 666</b>	<b>-10 354</b>	<b>Operating income/loss(-)</b>	<b>26 310</b>	<b>-33 491</b>	<b>-47 252</b>
2 683	5 738	Financial income	6 504	9 489	10 178
-831	-227	Financial expenses	-2 617	-1 100	-1 400
<b>1 852</b>	<b>5 511</b>	<b>Net financial income</b>	<b>3 887</b>	<b>8 390</b>	<b>8 778</b>
<b>-11 815</b>	<b>-4 842</b>	<b>Income/loss(-) before tax</b>	<b>30 197</b>	<b>-25 101</b>	<b>-38 474</b>
-	-	Tax expenses	-	-	-
<b>-11 815</b>	<b>-4 842</b>	<b>Net income/loss(-)</b>	<b>30 197</b>	<b>-25 101</b>	<b>-38 474</b>
-153	-47	Incl. minority interests in the amount of	-274	-89	-264
-0.61	-0.28	Net income/loss(-) per share, basic (1)	1.43	-1.43	-2.19
-0.61	-0.28	Net income/loss(-) per share, diluted	1.43	-1.43	-2.19

(1) Basic income/loss per share is calculation based on average weighted number of shares outstanding.

(2) Diluted income per share is calculated adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares.

**Segment Information**

**Income statement - geographical distribution**

(Amounts in NOK 1000)	3Q06				3Q05			
	Nordic	ROW	Un-allocated	Total	Nordic	ROW	Un-allocated	Total
Sales revenue	4 549	10 026		14 575	2 891	4 431	0	7 322
Milestone revenue	0	3 908		3 908	0	3 908	0	3 908
<b>Total revenues</b>	<b>4 549</b>	<b>13 934</b>	<b>0</b>	<b>18 484</b>	<b>2 891</b>	<b>8 339</b>	<b>0</b>	<b>11 230</b>
Cost of goods sold	425	3 628	0	4 053	392	2 000	0	2 392
<b>Gross profit</b>	<b>4 125</b>	<b>10 306</b>	<b>0</b>	<b>14 431</b>	<b>2 499</b>	<b>6 339</b>	<b>0</b>	<b>8 838</b>
Gross profit %	91 %	74 %		78 %	86 %	76 %		79 %
Operating expenses	4 712	-28	23 413	28 097	2 716	0	16 477	19 193
<b>Operating profit</b>	<b>-588</b>	<b>10 334</b>	<b>-23 413</b>	<b>-13 666</b>	<b>-218</b>	<b>6 339</b>	<b>-16 477</b>	<b>-10 355</b>
Net finance	0	0	1 852	1 852	0	0	5 511	5 511
<b>Profit before tax</b>	<b>-588</b>	<b>10 334</b>	<b>-21 561</b>	<b>-11 815</b>	<b>-218</b>	<b>6 339</b>	<b>-10 966</b>	<b>-4 844</b>

**Sales revenues - product split**

(Amounts in NOK 1000)	3Q06			3Q05		
	Nordic	ROW	Total	Nordic	ROW	Total
Metvix/Aktelite	3 740	7 207	10 947	2 728	4 363	7 091
Hexvix	809	2 819	3 628	163	68	230
<b>Total</b>	<b>4 549</b>	<b>10 026</b>	<b>14 575</b>	<b>2 891</b>	<b>4 431</b>	<b>7 322</b>

ROW=Rest Of the World



Balance Sheet (all amounts in NOK 1,000)

	2006 30.09	2005 30.09	2005 31.12
Machinery & equipment	3 594	2 273	2 708
Financial fixed assets	-	0	0
<b>Total fixed assets</b>	<b>3 594</b>	<b>2 273</b>	<b>2 708</b>
<b>Current assets</b>			
Inventory	13 524	14 591	12 943
Receivables	31 533	20 999	17 725
Cash & cash equivalents	271 474	80 975	72 329
<b>Total current assets</b>	<b>316 531</b>	<b>116 564</b>	<b>102 996</b>
<b>Total assets</b>	<b>320 124</b>	<b>118 837</b>	<b>105 704</b>
<b>Equity and liabilities</b>			
<b>Equity</b>			
Paid-in capital	259 619	67 145	67 145
Other paid-in capital	6 307	4 427	4 764
Retained earnings	5 114	-10 152	-23 444
<b>Shareholders' equity</b>	<b>271 040</b>	<b>61 420</b>	<b>48 465</b>
Minority interest	-	81	-
<b>Total equity</b>	<b>271 040</b>	<b>61 500</b>	<b>48 465</b>
<b>Liabilities</b>			
<b>Long-term liabilities</b>			
Retirement benefit obligations	-	105	-
Other non-current liabilities	-	300	300
<b>Total long-term liabilities</b>	<b>-</b>	<b>405</b>	<b>300</b>
<b>Current liabilities</b>	<b>49 085</b>	<b>56 932</b>	<b>56 939</b>
<b>Total liabilities</b>	<b>49 085</b>	<b>57 337</b>	<b>57 239</b>
<b>Total equity and liabilities</b>	<b>320 124</b>	<b>118 837</b>	<b>105 704</b>

Changes in equity (all amounts in NOK 1,000)

Three months ended			Nine months ended		2005
30.09.2006	30.09.2005		30.09.2006	30.09.2005	31.12
283 782	65 957	<b>Equity at beginning of period</b>	48 465	85 566	85 566
197	52	Share issue, employees	1 867	52	52
-	-	Share issue	190 608	-	-
514	334	Share-based compensation	1 542	983	1 320
-1 639	-	Fair value gains/losses(-)	-1 639	-	-
-11 815	-4 842	Net income/loss(-) for the period	30 197	-25 101	-38 474
<b>271 040</b>	<b>61 500</b>	<b>Equity at end of period</b>	<b>271 040</b>	<b>61 500</b>	<b>48 465</b>

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

Three months ended			Nine months ended		2005
30.09.2006	30.09.2005		30.09.2006	30.09.2005	01.01 - 31.12
-11 815	-4 842	Income/loss(-) before tax	30 197	-25 101	-38 474
-6	-18	Interest paid	-24	-50	-63
-709	-14 223	Other operational items	-26 042	-31 962	-32 004
<b>-12 530</b>	<b>-19 083</b>	<b>Net cash flow from operations</b>	<b>4 131</b>	<b>-57 113</b>	<b>-70 540</b>
942	-95	Cash flow from investments	2 840	684	5 464
197	52	Cash flow from capital transactions	192 174	-548	-548
<b>-11 390</b>	<b>-19 127</b>	<b>Net change in cash during the period</b>	<b>199 145</b>	<b>-56 978</b>	<b>-65 624</b>
282 864	100 102	Cash & cash equivalents at beginning of period	72 329	137 953	137 953
<b>271 474</b>	<b>80 975</b>	<b>Cash &amp; cash equivalents at end of period</b>	<b>271 474</b>	<b>80 975</b>	<b>72 329</b>