Photocure ASA - Third Quarter Report 2008

Highlights

- **Sales revenues increase 52% to NOK 23.6 million (from NOK 15.6 million in third quarter 2007)**
- **Operating profit improved by NOK 13.7 million to NOK -12.7 million (-26.5)**
- **First commercial sale of Metvixia®/Aktilite® to Galderma in the USA following its approval by the US Food and Drug Administration for the treatment of actinic keratosis**
- **Clinical data from the Hexvix® phase III study in the detection and recurrence rates of bladder cancer confirmed the medical benefit of Hexvix in patients with superficial bladder cancer**
- **Significant positive clinical outcome from the Visonac® phase IIb study and finalisation of the phase II program with Visonac for treatment of patients with moderate to severe acne.**
- **Liquid assets amounted to NOK 181.6 million at the end of the period**

Hexvix – sales revenue increased 69% compared to the third quarter of 2007
The work being done to introduce Hexvix bladder cancer diagnostic in Europe by Photocure and GE Healthcare, Photocure's commercial partner for Hexvix outside the Nordic regions, is progressing very well with Germany and Denmark being the most advanced markets.

As a result of this increased activity and the growing acceptance of photodynamic technology, sales revenue from Hexvix increased 69% in the third quarter of 2008 to NOK 7.8 million from NOK 4.6 million in the third quarter of 2007. Sales revenues from GE Healthcare were NOK 5.2 million in the third quarter of 2008, compared to NOK 3.5 million in the third quarter of 2007. Hexvix sales in units from GE Healthcare increased by 78% from 2,573 units in the third quarter of 2007 to 4,575 units in the third quarter of 2008. Photocure sales revenues from the Nordic countries more than doubled to NOK 2.6 million in the third quarter of 2008, compared to NOK 1.1 million in the third quarter of 2007. Hexvix sales in units from own sales increased from 341 units in the third quarter of 2007 to 808 units in the third quarter of 2008.

The UK National Health Service (NHS) announced in September 2008 a program designed to promote the adoption of photodynamic diagnosis of bladder cancer as standard care. Hexvix is currently the only photodynamic diagnostic product approved in the UK for detecting bladder cancer, where it is being commercialized by GE Healthcare. According to Cancer Research UK, more than 10,200 people were diagnosed with bladder cancer in the UK in 2005, and bladder cancers caused just over 4,800 deaths in the UK in 2006.

Hexvix Phase III study results demonstrate that improved diagnosis of bladder cancer with Hexvix leads to significantly improved patient outcome
Results from a new phase III clinical study, announced in September, show that fluorescence cystoscopy of the bladder using Hexvix (hexaminolevulinate) significantly improves the detection of non-invasive papillary bladder cancer. As a result of this improved procedure, more cancerous and

precancerous lesions can be removed than when standard cystoscopy is used, and this significantly improves patient outcome by reducing the recurrence of bladder cancer after nine months follow-up.

The phase III study results were generated from a large, multi-center trial comparing Hexvix cystoscopy to standard cystoscopy, and involved 789 patients with bladder cancer at 28 leading hospitals in the USA and Europe. Lesions identified in all patients were resected using the standard TURB procedure. The study ended in 2008 and patients were followed for possible disease recurrence for nine months after initial white light cystoscopy or Hexvix cystoscopy.

The results from the intention to treat (ITT) analysis show that in the patients receiving Hexvix cystoscopy, the detection of non-invasive bladder cancer was significantly improved (p=0.001) compared to standard cystoscopy. These results confirm the findings from Photocure's previously completed phase III studies.

In addition, the results of this phase III study showed that the recurrence of bladder cancer lesions in patients who received Hexvix cystoscopy compared to standard cystoscopy was significantly reduced (p=0.026) nine months after the initial cystoscopy and tumor resection procedure.

This latest phase III study was conducted under a Special Protocol Assessment (SPA). Further, Photocure has been in dialog with FDA and this new data will be a key part of the additional information Photocure intends to submit in its response to FDA towards gaining approval for Hexvix in the USA.

Metvix/Aktilite – sales revenue increased 45% compared to the third quarter 2007 and first commercial sale to Galderma in the US

Photocure received approval of Metvixia/Aktilite for actinic keratosis (AK) in the USA in June 2008. Galderma, Photocure's commercial partner for Metvixia/Aktilite, received the first shipment of Metvixia/Aktilite in the USA in September 2008.

Sales revenues from Metvix/Aktilite increased 45% to NOK 15.8 million in the third quarter of 2008 compared to NOK 10.9 million in the third quarter of 2007. Photocure's own sales from the Nordic countries increased 21% to NOK 6.0 million in the third quarter of 2008 compared to NOK 5.0 million in the same period 2007. The increase is a result of price increases in Norway and Sweden in 2007 as Metvix sales in units from own sales decreased from 3,822 units in the third quarter of 2007 to 3,263 units in the third quarter of 2008. Sales revenues from Galderma were NOK 9.8 million, an increase of 64% compared to the third quarter of 2007. The increased sales revenues were due to the sale of 87 Aktilite lamps in the third quarter of 2008 compared to 31 Aktilite lamps in the third quarter of 2007 and a 29% increase in prescription of Metvix to 12,294 units in the third quarter of 2008.

In August 2008, a new study was published documenting that PDT treatment with Metvix is effective in preventing new AK lesions in organ transplant patients. Organ transplant recipients on long-term immunosuppressive therapy are at increased risk of non-melanoma skin cancer, including AK. This increased risk of developing skin cancer increases with graft survival time and the duration of immunosuppressive therapy. Together, these factors contribute to substantially increased morbidity and mortality in transplant recipients compared with the general population. The open randomized, intrapatient, comparative, multi-center study confirmed that repeated field treatment with Metvix is effective as a safe and preventive treatment of pre-malignant skin lesions in organ transplant recipients receiving long-term immunosuppressive therapy.

The study was conducted at 11 hospital dermatology outpatient centers in Europe. Eighty-one transplant recipients with 889 lesions (90% AK) participated in the study. Each patient was treated in two areas on the face, scalp, neck, trunk or extremities; one area was treated with Metvix (treatment area), while the control area was treated at the investigator's discretion, mainly cryotherapy or surgery. At three months, Metvix significantly reduced the occurrence of new AK lesions, with 46% reduction (P=0.006) versus routine treatment (mainly cryotherapy). Patients who had undergone organ transplantation within the past ten years showed an even greater reduction (61%). In addition, Metvix treatment showed significant improvement in the cosmetic outcome.

Progress in clinical development programs

Photocure has a strong platform based on photodynamic technologies with a portfolio of three pipeline projects: Visonac™ to treat moderate to severe acne; Cevira™ to treat cellular abnormalities of the cervix; and Lumacan™, a fluorescence-based photodynamic product for detection of precancerous lesions in colon. All projects have made encouraging progress during the third quarter:

Visonac™ – treatment of moderate to severe acne

Visonac is a novel second-generation treatment for moderate to severe acne based on Photocure's patented PDT technology using the light-activated therapeutic compound methyl aminolevulinate.

In August 2008, Photocure announced positive preliminary results from two phase II studies carried out with Visonac. The first study showed that Visonac achieved similar efficacy results when compared to previous PDT approaches for the treatment of acne but was much better tolerated, while the second study confirmed that the overall Visonac procedure could be simplified.

Visonac treatment demonstrates excellent efficacy with reduced pain and redness

The larger of the two phase II studies recruited 150 patients from 14 sites in the USA. The primary aim of the study was to establish an effective dose of Visonac that was well tolerated. This study was blinded and the patients were randomized into three treatment groups: 8% Visonac cream plus red light illumination, 4% Visonac cream plus red light illumination and vehicle cream (containing no Visonac) plus red light illumination.

In this study a significant dose efficacy relationship of the Visonac was demonstrated. The efficacy results from this study are similar to the results shown in previous studies. A broad therapeutic window was demonstrated.

In addition, a second Visonac study clearly showed that the efficacy of the Visonac cream for the treatment of acne could be maintained without the use of occlusive dressing. This is also an important finding as it is anticipated that this simpler procedure would be much more appealing to dermatologists thereby making them more willing to treat moderate to severe acne patients with Visonac.

The final results from these two studies will provide Photocure with important information to design its phase III program. The results from these studies will be presented to the FDA and European regulatory agencies prior to beginning the phase III program for Visonac, with a possible start during first half 2009.

The new acne lamp, Aktilite® CL512, has moved into production and the first ten lamps were produced in September 2008.

Cevira™ – treatment of abnormalities in the cervix
Cevira is a photodynamic treatment of HPV (human papilloma virus) infection and precancerous and/or cancerous lesions in the cervix. Patient recruitment is completed in the ongoing phase I/II study. All patients will be followed for 12 months. Preliminary data after six months follow-up will be published in the fourth quarter of 2008. These data will give valuable input in the development of an optimal treatment for patients with abnormalities in the cervix.

A pre-IND meeting was held with FDA in April 2008 to discuss the development program and an IND was opened in third quarter of 2008.

Lumacan™ – diagnosis of colon cancer
Lumacan is a fluorescence-based photodynamic product for the detection of precancerous lesions in the colon. It builds on Photocure's extensive knowledge of early detection of bladder cancer using Hexvix. The first phase I/II clinical dose-finding study using a local instillation of Lumacan, involved 38 patients and the final results were presented at the Digestive Disease Week in San Diego, CA, in May 2008. The study showed excellent results: 52 of 53 (98%) premalignant/malignant lesions were positively detected using Lumacan while only 38 of 53 (72%) lesions were detected using standard white light colonoscopy.

These encouraging results have led to the pharmaceutical development of an oral formulation that has been completed successfully. A clinical study to examine the efficacy of this oral formulation has been designed and the study is planned to start in Germany by the end of this year.

Third quarter 2008 financial results
Sales revenues were NOK 23.6 million in the third quarter of 2008, compared to NOK 15.6 million in the third quarter of 2007, an increase of 52%. The increase is split on NOK 3.2 million higher Hexvix sales and NOK 4.9 million higher Metvix/Aktilite sales.

The gross margin, ex milestone revenues, increased from 78% in the third quarter of 2007 to 81% in the third quarter 2008. The increase is caused by higher royalty based sale from partners and effects of Metvix price increases in Norway and Sweden late in 2007.

Operating profit improved by NOK 13.7 million to NOK -12.7 million in the third quarter of 2008, compared to NOK -26.5 million in the third quarter of 2007. Research and development expenses decreased by NOK 12.5 million and the marketing and sales expenses decreased by NOK 0.8 million compared to the third quarter of 2007. The reduction in research and development expenses reflects completion of clinical studies in 2008. The decrease in marketing and sales expenses is attributable to variances in commercial activities compared to the third quarter of 2007.

Net financial profit for Photocure in the third quarter 2008 was NOK 0.7 million compared to net financial profit of NOK 2.8 million in the third quarter 2007.

Net profit was NOK -12.1 million in the third quarter of 2008 versus a net profit of NOK -23.6 million in the third quarter of 2007.

Year-to-date 2008 financial results
Sales revenues for the first nine months of 2008 were NOK 67.7 million, an increase of 31% compared to NOK 51.7 million in the first nine months of 2007. The increase is attributable to NOK 11.1 million higher sales of Hexvix and NOK 5.0 million higher sales of Metvix/Aktilite.

The gross margin, ex milestone revenues, increased from 72% in the first nine months of 2007 to 81% in the first nine months of 2008. The increase is due to higher royalty payments from partners and the effects of Metvix price increases in Norway and Sweden in 2007.

Operating profit amounted to NOK -52.9 million in the first nine months of 2008, compared to NOK -67.2 million in the first nine months of 2007. Research and development expenses decreased by NOK 24.4 million and the marketing and sales expenses increased by NOK 5.0 million compared to the first nine months of 2007. The reduction in research and development expenses reflects completion of clinical studies. The increase in marketing and sales expenses reflects a higher headcount and increased activities in 2008.

Net financial profit for the first nine months of 2008 was NOK -2.2 million compared to NOK 8.5 million in the first nine months of 2007. The net financial profit for 2008 includes an adjustment to market value of NOK -9.2 million to NOK 12.4 million for Photocure's 19.9 % ownership in PCI Biotech Holding ASA.

Net profit for the first nine months of 2008 amounted to NOK -55.1 million compared to a net profit of NOK -58.7 million in the first nine months of 2007.

Total equity for the group totalled NOK 208.6 million at the end of September 2008 compared to NOK 260.0 million at the end of 2007. Liquid funds amounted to NOK 181.6 million at the end of September 2008, compared to NOK 252.5 million at the end of 2007. The decrease in cash is influenced by the initial public offering of PCI Biotech Holding ASA where Photocure invested NOK 21.6 million. Photocure's cash & cash equivalents are placed in money market funds in Norway.

The number of outstanding shares was 22,093,301 at the end of September 2008.

The Board of Directors
Photocure ASA
Oslo, 23 October 2008

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Financial information

The unaudited financial information has been prepared in accordance with IAS 34 Interim Financial Statements and the principles used for preparation of the Annual Report 2007:

Profit & Loss (group - unaudited)

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

Q3 2008	Q3 2007		2008 1.1-30.09	2007 1.1-30.09	2007 1.1-31.12
23 629	15 565	Sales revenues	67 727	51 665	75 252
0	3 908	Signing fee and milestone revenues	1 303	19 845	23 754
23 629	**19 474**	**Total revenues**	**69 030**	**71 511**	**99 006**
-4 572	-3 374	Cost of products sold	-13 160	-14 359	-17 326
19 058	**16 100**	**Gross profit**	**55 870**	**57 152**	**81 679**
823	1 074	Other income	5 035	4 437	7 625
-2 202	-1 274	Indirect manufacturing expenses	-6 820	-6 914	-8 512
-16 188	-28 677	Research and development expenses	-58 795	-83 225	-112 098
-9 476	-10 276	Marketing and sales expenses	-33 357	-28 337	-39 766
-4 764	-3 405	General and administrative expenses	-14 838	-10 264	-16 378
-12 748	**-26 458**	**Operating profit/loss(-)**	**-52 905**	**-67 150**	**-87 450**
1 333	3 299	Financial income	8 453	9 572	14 224
-674	-462	Financial expenses	-10 684	-1 083	-1 744
659	**2 838**	**Net financial profit/loss(-)**	**-2 231**	**8 488**	**12 480**
-12 090	**-23 621**	**Profit/loss(-) before tax**	**-55 135**	**-58 662**	**-74 970**
0	0	Tax expenses	0	0	0
-12 090	**-23 621**	**Net profit/loss(-)**	**-55 135**	**-58 662**	**-74 970**
-	-406	Incl. minority interests in the amount of	-375	-728	-773
-0,55	-1,07	Net income/loss(-) per share, undiluted (1)	-2,50	-2,66	-3,40
-0,55	-1,07	Net income/loss(-) per share, diluted (2)	-2,49	-2,65	-3,39

(1) Undiluted 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.

Income statement Third Quarter 2008 - own sales/partner sales (unaudited)

	3Q 2008				% vs. PY	3Q 2007			
	Own	Partner	R&D*	Total		Own	Partner	R&D*	Total
Sales revenue	8 617	15 013	0	23 629	*52 %*	6 061	9 504	0	15 565
Milestone revenue	0	0	0	0		0	3 908	0	3 908
Total revenues	**8 617**	**15 013**	**0**	**23 629**	*21 %*	**6 061**	**13 412**	**0**	**19 474**
Cost of goods sold	493	4 079	0	4 572	*36 %*	559	2 815	0	3 374
Gross profit	**8 124**	**10 934**	**0**	**19 058**	*18 %*	**5 503**	**10 597**	**0**	**16 100**
Gross profit (ex milestones)	*94 %*	*73 %*		*81 %*		*91 %*	*70 %*		*78 %*
Operating expenses	8 351	4 644	18 812	31 807	*-25 %*	8 563	2 577	31 418	42 559
Operating profit	**-227**	**6 290**	**-18 812**	**-12 749**	*-52 %*	**-3 061**	**8 020**	**-31 418**	**-26 459**
Net finance	0	0	0	659	*-77 %*	0	0	0	2 838
Profit before tax	**-227**	**6 290**	**-18 812**	**-12 090**	*-49 %*	**-3 061**	**8 020**	**-31 418**	**-23 621**

** Including share of general and administrative expenses*

Sales revenues - product split

	3Q 2008			% vs. PY	3Q 2007		
	Own	Partner	Total		Own	Partner	Total
Metvix/Aktilite	5 996	9 807	15 803	*45 %*	4 964	5 970	10 935
Hexvix	2 620	5 206	7 826	*69 %*	1 097	3 533	4 631
Total	**8 617**	**15 013**	**23 629**	*52 %*	**6 061**	**9 504**	**15 565**

Income statement accumulated 1-3Q 2008 - own sales/partner sales (unaudited)

	1-3Q 2008				% vs. PY	1-3Q 2007			
	Own	Partner	R&D*	Total		Own	Partner	R&D*	Total
Sales revenue	24 296	43 431	0	67 727	*31 %*	19 439	32 227	0	51 665
Milestone revenue	0	1 303	0	1 303		0	19 845	0	19 845
Total revenues	**24 296**	**44 734**	**0**	**69 030**	*-3 %*	**19 439**	**52 072**	**0**	**71 511**
Cost of goods sold	1 621	11 539	0	13 160	*-8 %*	1 925	12 434	0	14 359
Gross profit	**22 675**	**33 196**	**0**	**55 870**	*-2 %*	**17 514**	**39 638**	**0**	**57 152**
Gross profit (ex milestones)	*93 %*	*73 %*		*81 %*		*90 %*	*61 %*		*72 %*
Operating expenses	28 381	14 178	66 217	108 776	*-12 %*	24 761	10 713	88 827	124 302
Operating profit	**-5 707**	**19 018**	**-66 217**	**-52 905**	*-21 %*	**-7 248**	**28 925**	**-88 827**	**-67 150**
Net finance	0	0	0	-2 231		0	0	0	8 488
Profit before tax	**-5 707**	**19 018**	**-66 217**	**-55 135**	*-6 %*	**-7 248**	**28 925**	**-88 827**	**-58 662**

** Including share of general and administrative expenses*

Sales revenues - product split

	1-3Q 2008			% vs. PY	1-3Q 2007		
	Own	Partner	Total		Own	Partner	Total
Metvix/Aktilite	17 474	26 945	44 418	*13 %*	15 411	24 018	39 430
Hexvix	6 822	16 487	23 309	*90 %*	4 027	8 208	12 236
Total	**24 296**	**43 431**	**67 727**	*31 %*	**19 439**	**32 227**	**51 665**

Balance Sheet (unaudited - all amounts in NOK 1,000)

	30.09.2008	30.09.2007	31.12.2007
Non-currrent assets			
Intangible assets, software	564	1 921	779
Machinery & equipment	3 826	2 617	3 436
Other investments	12 397		
Total non-current assets	**16 788**	**4 538**	**4 215**
Currrent assets			
Inventory	12 350	10 872	12 504
Receivables	24 412	27 917	32 222
Cash & cash equivalents	181 578	271 682	252 452
Total current assets	**218 339**	**310 470**	**297 179**
Total assets	**235 127**	**315 009**	**301 394**
Equity and liabilities			
Equity			
Paid-in capital	11 047	261 785	11 047
Other paid-in capital	15 086	9 452	10 984
Retained earnings	182 428	3 554	237 472
Shareholders' equity	**208 560**	**274 790**	**259 503**
Minority interest		0	491
Total equity	**208 560**	**274 790**	**259 994**
Liabilities			
Current liabilities	26 567	40 219	41 400
Total liabilities	**26 567**	**40 219**	**41 400**
Total equity and liabilities	**235 127**	**315 009**	**301 394**

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

Q3 2008	Q3 2007		2008 1.1-30.09	2007 1.1-30.09	2007 1.1-31.12
219 282	**296 650**	**Equity at beginning of period**	**259 994**	**326 935**	**326 935**
0	884	Share issue, employees	0	2 165	2 165
0		Share issue	0	1 720	1 720
1 368	877	Share-based compensation	4 103	2 631	4 163
		De-merger of PCI Biotech, capital decrease	-45 715	0	-20
		Net gain de-consolidation PCI Biotech	45 315		
-12 090	-23 621	Net income/loss(-) for the period	-55 135	-58 662	-74 970
208 560	**274 790**	**Equity at end of period**	**208 560**	**274 790**	**259 994**
			0		

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

Q3 2008	Q3 2007		2008 1.1-30.09	2007 1.1-30.09	2007 1.1-31.12
-12 090	-23 621	Income/loss(-) before tax	-55 135	-58 662	-74 970
-1 303	-7 271	Other operational items	-12 102	-13 353	-20 685
-13 393	**-30 892**	**Net cash flow from operations**	**-67 237**	**-72 015**	**-95 655**
-1 485	-189	Cash flow from investments	-6 725	5 036	9 450
-4	873	Cash flow from capital transactions	3 089	3 575	3 572
-14 881	**-30 208**	**Net change in cash during the period**	**-70 874**	**-63 404**	**-82 633**
196 460	301 890	Cash & cash equivalents at beginning of period	252 452	335 085	335 085
181 578	**271 682**	**Cash & cash equivalents at end of period**	**181 578**	**271 682**	**252 452**