



## Second Quarter Report 2009

### Highlights

(2Q 2008 figures in parenthesis)

- **Sales revenues increased 27% to NOK 28.9 million (NOK 22.7 million)**
- **Operating profit improved by NOK 3.2 million to NOK -14.5 million (NOK -17.7 million)**
- **Liquid funds amounted to NOK 150.6 million at the end of the period.**
- **Submitted NDA for Hexvix® in the USA.**

### **Hexvix® – sales revenue increased by 46% from second quarter 2008**

The work being done to introduce Hexvix bladder cancer diagnostic in Europe by Photocure and GE Healthcare, our commercial partner for Hexvix outside the Nordic region, is progressing very well. Today, Germany and Denmark are the most advanced markets, but large markets like Great Britain and France are developing well.

As a result of the growing acceptance of our photodynamic approach, sales revenue from Hexvix increased by 46% in the second quarter of 2009 to NOK 11.9 million compared to NOK 8.2 million in the second quarter of 2008. Sales revenue from GE Healthcare was NOK 7.4 million in the second quarter of 2009, compared to NOK 6.2 million in the second quarter 2008.

Hexvix sales in units from GE Healthcare increased with 5% from 5,235 in the second quarter 2008 to 5,497 units in the second quarter 2009. Hexvix sales in units from the Nordic region more than doubled, and was 1,257 in the second quarter 2009 compared to 595 units in the second quarter 2008. The growth in the Nordic region is attributable to reimbursement and acceptance in key hospitals in Denmark and Finland. In the second quarter 2009, Hexvix is used in approximately 50% of all TURB-procedures in Denmark. With this share Hexvix is considered standard treatment or "Gold Standard" for these procedures.

In June 2009, Photocure submitted the NDA for Hexvix in the USA. The NDA targets detection of superficial bladder cancer with fluorescence diagnostics and was based on clinical data from more than 1,800 patients, including two phase III studies with more than 1,000 patients. The clinical data demonstrates a significant improvement in detection of bladder cancer as well as a significant reduction in recurrence compared to standard white light cystoscopy.

Sales revenue from Hexvix increased 39% to NOK 21.6 million in the first half of 2009 compared to NOK 15.5 million in the first half of 2008. Sales revenue from GE Healthcare was NOK 13.2 million in the first half of 2009. Sales revenue from Photocure's own sales was NOK 8.3 million in the first half of 2009.

### **Metvix®/Aktelite® – end user sale of Metvix tubes increased with 25% in the Nordic area**

Sales revenue from Metvix/Aktelite, for the photodynamic treatment (PDT) of cancerous and precancerous skin lesions, in the second quarter of 2009 was NOK 17.0 million compared to NOK 14.5 million in the second quarter of 2008, an increase of 17%. Sales revenue from Galderma, our commercial partner for Metvix/Aktelite outside the Nordic region, increased by 29% to NOK 11.2 million for the period, compared to NOK 8.7 million in the second quarter of 2008 despite the very limited sales in the USA. Sales in the Nordic region by Photocure were NOK 5.8 million in the second quarter of 2009, the same as the second quarter 2008.



Galderma increased the sales of Metvix tubes in units by 4 % to 15,498 units in the second quarter of 2009. Metvix sales in units from own sales increased with 25% from 2,731 in the second quarter of 2008 to 3,418 units in the second quarter of 2009, mainly as a result of the high level of activities over the last years og indicates that the product has a higher potential.

Sales revenue from Metvix/Aktilite increased 27% to NOK 36.4 million in the first half of 2009 compared to NOK 28.6 million in the first half of 2008. Sales revenue from Galderma was NOK 22.5 million in the first half of 2009. Sales revenue from Photocure's own sales was NOK 13.9 million in the first half of 2009.

### **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™, our new fluorescence-based photodynamic diagnostic product for detection of precancerous lesions in colon. All projects have made encouraging progress during the second quarter:

#### ***Visonac™ – treatment of moderate to severe acne***

Visonac is a novel topical treatment for moderate to severe acne based on Photocure's patented PDT technology. Photocure had meetings with regulatory authorities in Europe and the US in the first half of 2009 to seek regulatory and scientific advice and discuss the results of the phase II data in addition to the design of the phase III program. The outcome of the meetings is that Photocure can start a phase III program in Europe based on the existing clinical data. FDA recommended collecting more data in a younger population down to 9 years with the new acne lamp. Photocure will start the new phase II study in the USA in third quarter 2009.

Start of a phase III study in Europe is planned for first quarter 2010. After planned completion of the phase II study in the USA, Photocure plans to have a meeting with the FDA in the second quarter 2010 to seek additional regulatory advice before initiation of the phase III program.

#### ***Cevira™ – treatment of abnormalities in the cervix***

Cevira is a new photodynamic treatment of HPV induced infection and precancerous and/or cancerous lesions in the cervix.

A new phase I/II clinical proof-of-concept study including up to 70 patients with low grade dysplasia (CIN1) started in the first quarter 2009. At the end of July 2009, 30 patients have been included. All patients will be followed for 12 months. The first report from the study is expected in the first half of 2010 after six months follow-up. The clinical data will give valuable information in developing an effective photodynamic treatment of the cervix with limited side-effects.

Photocure has developed a novel method for simple and effective application of drug combined with illumination of the cervix. The new device will be tested in the second half of 2009.

#### ***Lumacan™ – diagnosis of colon cancer***

Lumacan is our fluorescence-based photodynamic diagnostic (PDD) product for the detection of precancerous lesions in colon. It builds on Photocure's extensive knowledge of using PDD for the early detection of bladder cancer via Hexvix.

A phase I/II clinical proof-of-concept study was started in the first quarter of 2009 using Lumacan administered orally. This study will include up to 70 patients in Germany. 9 patients are included as of today and the study will investigate the efficacy of a new oral formulation. The results are planned to be reported in first quarter of 2010.



Photocure plans to conduct a pharmacokinetic study in fourth quarter of 2009 in order to investigate the absorption of hexylaminolevulinat in the colon and the cervix. The study will end in first quarter of 2010.

#### **Patent term extension for Metvixia™ in the USA is appealed by USPTO**

In September 2004, Photocure submitted to the United States Patent Office (USPTO) an application for patent term extension of its US patent covering its FDA-approved drug product Metvixia™. US law permits patent term extension due to the lengthy Food and Drug Administration (FDA) approval process, which had been the case for Metvixia™. The USPTO denied Photocure's application and Photocure sought judicial relief by appealing the USPTO's decision.

Based upon Photocure's appeal, the US Eastern District Court of Virginia granted summary judgment in Photocure's favour in April 2009. In its decision the Court stated that the USPTO's interpretation of the law is not reasonable. The matter was remanded back to the USPTO to take appropriate steps on granting the requested patent term extension for Metvixia™. USPTO appealed the judgement in June 2009. Hearing for a higher court is scheduled for September 6, 2009.

Photocure has a patent covering Metvixia™ in USA until March 2016. Based on the outcome of the patent term extension case, this patent may be extended to July 27, 2018.

#### **Second Quarter 2009 Financial Results (unaudited)**

Sales revenues were NOK 28.9 million in the second quarter of 2009, compared to NOK 22.7 million in the second quarter of 2008, an increase of 27%. The sales increase is split on NOK 3.7 million higher Hexvix sales and NOK 2.5 million higher Metvix/Aktillite sales.

The gross margin increased from 82% in the second quarter of 2008 to 83% in the second quarter 2009.

Operating profit was NOK -14.5 million in the second quarter 2009, compared to NOK -17.7 million in the second quarter of 2008. Research and development expenses decreased by NOK 0.4 million and the marketing and sales expenses decreased by NOK 1.2 million compared to the second quarter of 2008. Close to half of the research and development expenses were related to Hexvix, including an NDA fee to FDA of USD 1.25 million. The decrease in marketing and sales expenses is attributable to two temporary vacancies in the Nordic region.

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The second quarter net financial gain was NOK 2.4 million.

Net profit for the second quarter of 2009 was NOK -12.1 million versus a net profit of NOK -23.0 million in the second quarter of 2008.

#### **Year-to-Date 2009 Financial Results (unaudited)**

Sales revenues for the first six month period of 2009 were NOK 58.0 million, an increase of 31% compared to NOK 44.1 million in the first six months of 2008. The sales increase is split on NOK 6.1 million higher Hexvix sales and NOK 7.8 million higher Metvix/Aktillite sales.

The gross margin, ex milestone revenues, increased from 81% in the first six months of 2008 to 84% in the first six-months of 2009.

Operating profit amounted to NOK -20.2 million in the first six month period of 2009, compared to NOK -40.2 million in the first six months of 2008. Research and development expenses decreased by NOK 9.7 million reflecting lower level of clinical activities. Marketing and sales expenses decreased by NOK 0.5 million compared to the first six months of 2008.



Net financial loss for the first six months of 2009 was NOK 0.5 million.

Net profit for the first six month period of 2009 was NOK -20.7 million compared to a net profit of NOK -43.0 million in the first half of 2008.

Total equity for Photocure was NOK 181.9 million at the end of June 2009 compared to NOK 199.7 million at the end of 2008. Liquid funds amounted to NOK 150.6 million at the end of June 2009, compared to NOK 179.9 million at the end of 2008. The decrease in cash is mainly due to cash flow from operations of NOK -33.7 million in the first six months of 2009. The number of outstanding shares was 22,093,301 at the end of June 2009.

### **Risks and uncertainty**

Photocure is exposed to uncertainties and risk factors, which may affect some or all of the Company's activities. Photocure has financial risk, market risk and operational risk factors, risk related to research and development of new products as well as risks related to the shares.

The most important risks the Company is exposed to for the last six months of 2009 are associated with progress and performance of the clinical development programs, market development for Metvix/Aktelite and Hexvix as well as financial risks related to interest rates, liquidity and currency fluctuations.

Photocure does not have any significant changes in the uncertainties and risks compared to the descriptions in the Annual Report for 2008.

### **Transactions with related parties**

Photocure has not been part of any transaction with related parties that has had significant impact on the Company's financial position in the first six month period of 2009.

### **Responsibility Statement**

We confirm that, to the best of our knowledge, the condensed set of financial statements for the first half year of 2009 which has been prepared in accordance with IAS 34 Interim Financial Statements gives a true and fair view of the Company's consolidated assets, liabilities, financial position and results of operations, and that the interim management reports includes a fair review of the information required under the Norwegian Securities trading Act section 5-6 fourth paragraph.

The Board of Directors/President & CEO  
Photocure ASA  
Oslo, 13 August 2009

Erik Engebretsen  
Chairman

Jon Hindar

Kari Krogstad

Mats Pettersson

Eva Steiness

Kjetil Hestdal  
President & CEO

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The following unaudited information is presented according to IAS 34 - Interim Financial Reporting. The accounting policies adopted in this report are consistent with those followed in the preparation of the Group's annual financial statements for 2008 except that the presentation has adapted the new requirements in IAS 1 - Presentation of Financial Statements.

Profit & Loss (unaudited). All amounts in NOK 1,000 except per share data:

Q2 2009	Q2 2008		2009 1.1-30.6	2008 1.1-30.6	2008 1.1-31.12
28 889	22 687	Sales revenues	57 962	44 098	100 917
0	0	Signing fee and milestone revenues	0	1 303	1 303
<b>28 889</b>	<b>22 687</b>	<b>Total revenues</b>	<b>57 962</b>	<b>45 401</b>	<b>102 220</b>
-5 009	-4 087	Cost of products sold	-9 538	-8 588	-19 074
<b>23 880</b>	<b>18 600</b>	<b>Gross profit</b>	<b>48 424</b>	<b>36 813</b>	<b>83 147</b>
1 461	2 257	Other income	2 023	4 211	6 257
-2 261	-2 108	Indirect manufacturing expenses	-4 929	-4 619	-8 607
-21 209	-21 627	Research and development expenses	-32 897	-42 607	-84 303
-10 689	-11 871	Marketing and sales expenses	-23 301	-23 881	-45 916
-5 687	-2 933	General and administrative expenses	-9 561	-10 074	-17 951
<b>-14 505</b>	<b>-17 683</b>	<b>Operating profit/loss(-)</b>	<b>-20 240</b>	<b>-40 156</b>	<b>-67 374</b>
3 094	4 151	Financial income	7 092	7 120	16 103
-684	-9 490	Financial expenses	-7 559	-10 010	-13 111
<b>2 410</b>	<b>-5 339</b>	<b>Net financial profit/loss(-)</b>	<b>-467</b>	<b>-2 890</b>	<b>2 991</b>
<b>-12 095</b>	<b>-23 022</b>	<b>Profit/loss(-) before tax</b>	<b>-20 706</b>	<b>-43 046</b>	<b>-64 382</b>
0	0	Tax expenses	0	0	0
<b>-12 095</b>	<b>-23 022</b>	<b>Net profit/loss(-)</b>	<b>-20 706</b>	<b>-43 046</b>	<b>-64 382</b>
1 048	0	Other comprehensive income	1 048	0	0
<b>-11 047</b>	<b>-23 022</b>	<b>Comprehensive income</b>	<b>-19 658</b>	<b>-43 046</b>	<b>-64 382</b>
-	-289	Incl. minority interests in the amount of	-	-375	-
-0.55	-1.04	Net profit/loss(-) per share, undiluted (1)	-0.94	-1.95	-2.91
-0.55	-1.04	Net profit/loss(-) per share, diluted (2)	-0.94	-1.95	-2.91

(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.



### Segment information

(Amounts in NOK 1000)	2Q 2009				% vs. PY	2Q 2008			
	Own	Partner	R&D*	Total		Own	Partner	R&D*	Total
Sales Metvix/Aktelite	5 816	11 166		16 982	17 %	5 838	8 688		14 526
Sales Hexvix	4 531	7 376		11 907	46 %	1 969	6 193		8 162
Sales revenue	10 347	18 541	0	28 889	27 %	7 807	14 881	0	22 687
Milestone revenue	0	0	0	0		0	0	0	0
<b>Total revenues</b>	<b>10 347</b>	<b>18 541</b>	<b>0</b>	<b>28 889</b>	<b>27 %</b>	<b>7 807</b>	<b>14 881</b>	<b>0</b>	<b>22 687</b>
Cost of goods sold	511	4 498	0	5 008	23 %	547	3 540	0	4 087
<b>Gross profit</b>	<b>9 836</b>	<b>14 044</b>	<b>0</b>	<b>23 880</b>		<b>7 259</b>	<b>11 341</b>	<b>0</b>	<b>18 600</b>
Gross profit %	95 %	76 %		83 %		93 %	76 %		82 %
Operating expenses	10 115	5 392	22 878	38 385	6 %	9 410	3 427	23 446	36 283
<b>Operating profit</b>	<b>-278</b>	<b>8 652</b>	<b>-22 878</b>	<b>-14 505</b>	<b>-18 %</b>	<b>-2 151</b>	<b>7 914</b>	<b>-23 446</b>	<b>-17 683</b>
Net finance	0	0	0	2 410		0	0	0	-5 339
<b>Profit before tax</b>	<b>-278</b>	<b>8 652</b>	<b>-22 878</b>	<b>-12 095</b>	<b>-47 %</b>	<b>-2 151</b>	<b>7 914</b>	<b>-23 446</b>	<b>-23 022</b>

\* Including share of general and administrative expenses

### Segment information

(Amounts in NOK 1000)	1H 2009				% vs. PY	1H 2008			
	Own	Partner	R&D*	Total		Own	Partner	R&D*	Total
Sales Metvix/Aktelite	13 897	22 489		36 385	27 %	11 477	17 138		28 615
Sales Hexvix	8 349	13 227		21 576	39 %	4 202	11 281		15 483
Sales revenue	22 246	35 716	0	57 962	31 %	15 679	28 419	0	44 098
Milestone revenue	0	0	0	0		0	1 303	0	1 303
<b>Total revenues</b>	<b>22 246</b>	<b>35 716</b>	<b>0</b>	<b>57 962</b>	<b>28 %</b>	<b>15 679</b>	<b>29 722</b>	<b>0</b>	<b>45 401</b>
Cost of goods sold	1 082	8 455	0	9 537	11 %	1 128	7 460	0	8 588
<b>Gross profit</b>	<b>21 164</b>	<b>27 261</b>	<b>0</b>	<b>48 425</b>		<b>14 551</b>	<b>22 262</b>	<b>0</b>	<b>36 813</b>
Gross profit %	95 %	76 %		84 %		93 %	75 %		81 %
Operating expenses	20 855	9 952	37 857	68 664	-11 %	20 031	9 534	47 404	76 968
<b>Operating profit</b>	<b>309</b>	<b>17 309</b>	<b>-37 857</b>	<b>-20 239</b>	<b>-50 %</b>	<b>-5 480</b>	<b>12 728</b>	<b>-47 404</b>	<b>-40 156</b>
Net finance	0	0	0	-467		0	0	0	-2 890
<b>Profit before tax</b>	<b>309</b>	<b>17 309</b>	<b>-37 857</b>	<b>-20 706</b>	<b>-52 %</b>	<b>-5 480</b>	<b>12 728</b>	<b>-47 404</b>	<b>-43 046</b>

\* Including share of general and administrative expenses



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

	30.06.2009	30.06.2008	31.12.2008
Intangible assets, software	472	615	534
Machinery & equipment	3 449	4 021	3 939
Other investments	8 384	12 397	11 528
<b>Total non-current assets</b>	<b>12 305</b>	<b>17 033</b>	<b>16 001</b>
Inventory	19 013	11 941	12 792
Receivables	30 617	25 000	29 158
Cash & cash equivalents	150 556	196 460	179 897
<b>Total current assets</b>	<b>200 185</b>	<b>233 401</b>	<b>221 846</b>
<b>Total assets</b>	<b>212 490</b>	<b>250 434</b>	<b>237 847</b>
Paid-in capital	11 047	11 047	11 047
Other paid-in capital	190 476	13 719	15 467
Retained earnings	-19 658	194 517	173 181
<b>Shareholders' equity</b>	<b>181 864</b>	<b>219 282</b>	<b>199 694</b>
Minority interest		0	
<b>Total equity</b>	<b>181 864</b>	<b>219 282</b>	<b>199 694</b>
Current liabilities	30 627	31 152	38 153
<b>Total liabilities</b>	<b>30 627</b>	<b>31 152</b>	<b>38 153</b>
<b>Total equity and liabilities</b>	<b>212 490</b>	<b>250 434</b>	<b>237 847</b>

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

Q2 2009	Q2 2008		2009 1.1-30.6	2008 1.1-30.6	2008 1.1-31.12
191 997	241 336	Equity at beginning of period	199 694	259 994	259 994
0	0	Share issue, employees	0	0	0
0	0	Share issue	0	0	0
914	1 368	Share-based compensation	1 828	2 735	4 483
0	-45 715	De-merger of PCI Biotech/ Investment	0	-45 715	-45 715
0	45 315	Net gain de-consolidation PCI Biotech	0	45 315	45 315
-11 047	-23 022	Comprehensive income	-19 658	-43 046	-64 382
<b>181 864</b>	<b>219 282</b>	<b>Equity at end of period</b>	<b>181 864</b>	<b>219 282</b>	<b>199 694</b>

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

Q2 2009	Q2 2008		2009 1.1-30.6	2008 1.1-30.6	2008 1.1-31.12
-12 095	-23 022	Profit/loss(-) before tax	-20 706	-43 046	-64 382
404	404	Depreciation and amortisation	802	784	1 554
914	1 368	Share-based compensation	1 828	2 735	4 483
-2 102	-3 319	Net interests	-4 612	-5 452	-10 260
0	9 163	Write down financial assets	4 192	9 163	9 432
-445	-10 710	Changes in working capital	-15 205	-7 238	-471
0	-1 427	Other operational items	0	-10 791	-35
<b>-13 324</b>	<b>-27 544</b>	<b>Net cash flow from operations</b>	<b>-33 703</b>	<b>-53 844</b>	<b>-59 679</b>
2 010	-16 068	Cash flow from investments	4 363	-5 240	-12 865
-2	3 095	Cash flow from capital transactions	-2	3 092	-13
<b>-11 316</b>	<b>-40 516</b>	<b>Net change in cash during the period</b>	<b>-29 341</b>	<b>-55 992</b>	<b>-72 556</b>
161 872	236 977	Cash & cash equivalents at beginning of period	179 897	252 452	252 452
<b>150 556</b>	<b>196 460</b>	<b>Cash &amp; cash equivalents at end of period</b>	<b>150 556</b>	<b>196 460</b>	<b>179 897</b>