



# Third Quarter Report 2009

## Highlights

(Q3 2008 figures in parenthesis)

- Sale of Metvix®/Aktelite® to Galderma for EUR 51 million.
- Total revenues of NOK 389.3 million (NOK 23.6 million)
- Operating profit of NOK 353.7 million (NOK -12.7 million)
- Cash & cash equivalents of NOK 512 million per 1 October 2009, consisting of NOK 140.3 million at 30 September 2009, in addition to EUR 44 million in cash from Galderma on 1 October 2009
- Photocure's Board of Directors propose an extraordinary dividend of NOK 4.00/share and initiation of a stock repurchase program
- Photocure's NDA for Hexvix® designated for priority review in the US

<i>NOK 000 (unaudited)</i>	Q3 09	Change	Q3 08	YTD 2009	Change	YTD 2008
Total revenues	389 257	1547 %	23 629	447 218	548 %	69 030
Gross profit	385 431	1922 %	19 057	433 855	677 %	55 870
R&D expenses	19 301	19 %	16 188	52 203	-11 %	58 795
Operating profit	353 749	N/A	-12 749	333 509	N/A	-52 905
Net profit	355 337	N/A	-12 090	334 630	N/A	-55 136
EPS, diluted (NOK)	16.08		-0.55	15.15		-2.49

## Strategy

The sale of Metvix/Aktelite to Galderma enables Photocure to implement its strategy to:

- Become a true specialty pharma company within dermatology with Visonac and other new dermatology products, based on a strong commercial platform
- Continue its commercialization of Hexvix for bladder cancer diagnostics in partnership with GE Healthcare
- Continue its development of the cancer portfolio, i.e. Cevira and Lumacan, and secure commercialization through out-licensing agreement prior to initiation of phase III studies as planned

This strategy is based on a strong platform of intellectual property in photodynamic therapy.

## Extraordinary dividend of NOK 4.00/share and initiation of a share repurchase program

Photocure's Board of Directors has decided to call an extraordinary general assembly and propose an extraordinary dividend of NOK 4.00/share. Furthermore, The Board has decided to initiate a



share repurchase program within the existing power of attorney limiting the repurchase up to 3 % of the outstanding shares, or 662,799 shares. The existing share purchase program will start as soon as practically possible. The Board has further decided to propose an extension of the share repurchase program up to 10 % of the outstanding shares at the extraordinary general meeting.

### **Sale of Metvix®/Aktilite® to Galderma for EUR 51 million**

On 1 October 2009, Photocure entered into agreements with Galderma, under which Galderma purchased global rights, assets, and liabilities related to Metvix® and Aktilite®, as well as the right to develop new dermatology products based on Photocure's patented substance, methylaminolevulinate (MAL). Photocure retain the right to develop and commercialize Visonac™ for acne based on MAL.

Galderma has, based on the agreement, taken over Photocure's Nordic marketing and sales organisation for Metvix.

Photocure received an initial payment of EUR 44 million and will receive future payments of EUR 7 million upon regulatory approval of new dermatology products based on MAL, with guaranteed payments of EUR 3 million by December 2012 and EUR 4 million by December 2016. These payments will thus replace any future milestone, royalty payments and product sales relating to Metvix®/Aktilite® and future MAL-based dermatology products except for Visonac™.

Sales revenues from Metvix/Aktilite in the third quarter of 2009 was NOK 13.8 million. This is not directly comparable to NOK 15.8 million in the third quarter of 2008 as Photocure did not receive royalty from Galderma for sale of Metvix in September 2009. Photocure's sales revenues of Metvix/Aktilite in the Nordic region was NOK 5.3 million in the third quarter of 2009, compared to NOK 6.0 million in the third quarter 2008.

### **Hexvix® – sales revenue increased by 59% from third quarter 2008**

Hexvix is marketed in Europe by Photocure and GE Healthcare, the company's commercial partner for Hexvix outside the Nordic region. Today, Germany and Denmark are the most advanced markets, but large markets like the UK and France are also developing well.

As a result of the growing acceptance of Hexvix, sales revenue increased by 59% in the third quarter of 2009 to NOK 12.5 million compared to NOK 7.8 million in the third quarter of 2008. Sales revenue from GE Healthcare was NOK 7.7 million in the third quarter of 2009, compared to NOK 5.2 million in the third quarter 2008. Sales revenue from own sales in the Nordic region was NOK 4.7 million in the third quarter of 2009, compared to NOK 2.6 million in the third quarter 2008. The growth in the Nordic region is due to increased acceptance in key hospitals in Denmark and Finland.

Hexvix sales in units from GE Healthcare to end-users increased by 18% from 4,575 in the third quarter 2008 to 5,376 units in the third quarter 2009. Hexvix sales in units to end-users from the Nordic region increased by 52% from 808 units in the third quarter 2008 to 1,226 units in the third quarter 2009.

### **FDA designated priority review for the Hexvix NDA**

In June 2009, Photocure submitted a New Drug Application (NDA) for Hexvix in the US. The NDA targets detection of superficial bladder cancer with fluorescence diagnostics.

The US Food and Drug Administration (FDA) designated priority review for the Hexvix NDA in August 2009. The standard target review time of an NDA is 10-12 months from the submission. A



priority review has a target review time of 6 months. FDA assigns priority review to products which the FDA considers to provide a significant improvement over current standard of care.

Hexvix has been approved for use in diagnosis of bladder cancer in Europe since 2005, and its usefulness is acknowledged by the fact that fluorescence cystoscopy, for which Hexvix is the only approved drug on the global market, is recommended in the European Association of Urology's guidelines. The cystoscopic procedure is used for bladder mapping, guiding of biopsies in suspect areas of the bladder and trans urethral resection of the bladder (TURB), i.e. removal of cancerous bladder tissue.

### **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 third 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 started the new phase II study in the US in August 2009. This study will include app. 100 patients and 62 patients are included to date.

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

#### ***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 phase I/II clinical proof-of-concept study including up to 70 patients with low grade dysplasia (CIN1) started in the first quarter of 2009. As of today, 44 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 first half of 2010.

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

Lumacan is a 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.

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. 13 patients are included as of today and the study will investigate the efficacy of different new oral formulations. Preliminary results are planned to be reported in first half of 2010.



### **Patent term extension case for Metvixia™ in the US 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 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 took place on September 6, 2009. A decision from the hearing is expected in 2009.

Photocure has a patent covering Metvixia™ in the US until March 2016. Based on the outcome of the patent term extension case, this patent may be extended to July 27, 2018. This patent case is important for Photocure's total patent portfolio in the US.

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

Sales revenues were NOK 26.3 million in the third quarter of 2009, compared to NOK 23.6 million in the third quarter of 2008, an increase of 11 %. The sales revenues reflects an increase of NOK 4.7 million from Hexvix and a decrease in Metvix/Aktilite sales of NOK 2.0 million. Photocure did not receive royalty for Metvix in September, as part of the agreement with Galderma.

Operating profit was NOK 353.7 million in the third quarter of 2009, compared to operating loss of NOK 12.7 million in the third quarter of 2008. The increase is by and large due to the Metvix transaction, from which Photocure has booked a net revenue of NOK 363 million in the third quarter 2009. Income related to the payment of EUR 7 million for new registrations will be accrued from October 2009 through December 2016.

Research and development (R&D) expenses increased by NOK 3.1 million and the marketing and sales expenses (M&S) increased by NOK 0.8 million compared to the third quarter of 2008. A major part of the R&D expenses were related to Visonac and the increase in clinical activities. The increase in M&S expenses is attributable to increased activities in the Nordic region.

Net profit for the third quarter of 2009 was NOK 355.3 million compared to a net loss of NOK 12.1 million in the third quarter of 2008.

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

Sales revenues for the first nine months of 2009 were NOK 84.2 million, an increase of 24 % compared to the NOK 67.7 million reported for the first nine months of 2008. NOK 10.7 million of the increase comes from higher Hexvix sales and NOK 5.8 million from increased Metvix/Aktilite sales.

Due to the Metvix transaction, operating profit amounted to NOK 333.5 million in the first nine months of 2009, compared to operating loss of NOK 52.9 million in the first nine months of 2008. R&D expenses decreased by NOK 6.6 million to NOK 52.2 million reflecting lower level of clinical activities in 2009. M&S expenses were NOK 33.6 million, an increase of NOK 0.2 million compared to the first nine months of 2008.

Net profit for the first nine month of 2009 was NOK 334.6 million compared to a net loss of NOK 55.1 million in the first nine months of 2008.



Total equity for Photocure was NOK 538.1 million at the end of September 2009 compared to NOK 199.7 million at the end of 2008. Liquid funds amounted to NOK 140.3 million at the end of September 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 –45.3 million in the first nine months of 2009. Photocure received EUR 44 million in cash on October 1<sup>st</sup>, 2009 related to the sale of Metvix/Aktelite. Cash and cash equivalents per 1 October 2009 was NOK 512 million. The number of outstanding shares was 22,093,301 at the end of September 2009.

The Board of Directors and the President & CEO  
Photocure ASA

Oslo, 27 October 2009

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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.

Statement of comprehensive income (unaudited). All amounts in NOK 1,000 except per share data:

**Statement of comprehensive income**

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

Q3 2009	Q3 2008		2009 1.1-30.9	2008 1.1-30.9	2008 1.1-31.12
26 270	23 629	Sales revenues	84 232	67 727	100 917
362 986	0	Signing fee and milestone revenues (1)	362 986	1 303	1 303
<b>389 257</b>	<b>23 629</b>	<b>Total revenues</b>	<b>447 218</b>	<b>69 030</b>	<b>102 220</b>
-3 825	-4 572	Cost of products sold	-13 363	-13 160	-19 074
<b>385 431</b>	<b>19 057</b>	<b>Gross profit</b>	<b>433 855</b>	<b>55 870</b>	<b>83 147</b>
4 035	823	Other income	6 059	5 035	6 257
-2 394	-2 202	Indirect manufacturing expenses	-7 323	-6 820	-8 607
-19 306	-16 188	Research and development expenses	-52 203	-58 795	-84 303
-10 327	-9 476	Marketing and sales expenses	-33 628	-33 357	-45 916
-3 690	-4 764	General and administrative expenses	-13 251	-14 838	-17 951
<b>353 749</b>	<b>-12 749</b>	<b>Operating profit/loss(-)</b>	<b>333 509</b>	<b>-52 905</b>	<b>-67 374</b>
2 649	1 333	Financial income	9 741	8 453	16 103
-1 062	-674	Financial expenses	-8 620	-10 684	-13 111
<b>1 588</b>	<b>659</b>	<b>Net financial profit/loss(-)</b>	<b>1 121</b>	<b>-2 231</b>	<b>2 991</b>
<b>355 337</b>	<b>-12 090</b>	<b>Profit/loss(-) before tax</b>	<b>334 630</b>	<b>-55 136</b>	<b>-64 382</b>
0	0	Tax expenses	0	0	0
<b>355 337</b>	<b>-12 090</b>	<b>Net profit/loss(-)</b>	<b>334 630</b>	<b>-55 136</b>	<b>-64 382</b>
0	0	Other comprehensive income	1 048	0	0
<b>355 337</b>	<b>-12 090</b>	<b>Comprehensive income</b>	<b>335 678</b>	<b>-55 136</b>	<b>-64 382</b>
-	-	Incl. minority interests in the amount of	-	-375	-
16.08	-0.55	Net profit/loss(-) per share, undiluted (2)	15.15	-2.50	-2.91
16.08	-0.55	Net profit/loss(-) per share, diluted (3)	15.15	-2.49	-2.91

(1) See separate specification.

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

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

**Specification Signing fee and milestone revenues (all amounts in NOK 1,000)**

	2009 1.1-30.9	2008 1.1-30.9	2008 1.1-31.12
Sale of Metvix/Aktelite business	373 560	0	0
Deferred signing fee	0	1 303	1 303
<b>Lisence and signing fees</b>	<b>373 560</b>	<b>1 303</b>	<b>1 303</b>
Direct costs sale of Metvix/Aktelite business	-7 231	0	0
Advisory and legal fees	-3 343	0	0
<b>Transaction costs</b>	<b>-10 574</b>	<b>0</b>	<b>0</b>
<b>Signing fee and milestone revenues</b>	<b>362 986</b>	<b>1 303</b>	<b>1 303</b>



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

	30.09.2009	30.09.2008	31.12.2008
Intangible assets, software	418	564	534
Machinery & equipment	2 074	3 826	3 939
Other investments	8 384	12 397	11 528
<b>Total non-current assets</b>	<b>10 876</b>	<b>16 788</b>	<b>16 001</b>
Inventory	11 870	12 350	12 792
Receivables	408 637	24 412	29 158
Cash & cash equivalents	140 311	181 578	179 897
<b>Total current assets</b>	<b>560 819</b>	<b>218 339</b>	<b>221 846</b>
<b>Total assets</b>	<b>571 695</b>	<b>235 127</b>	<b>237 847</b>
Paid-in capital	11 047	11 047	11 047
Other paid-in capital	191 390	15 086	15 467
Retained earnings	335 678	182 428	173 181
<b>Total equity</b>	<b>538 114</b>	<b>208 560</b>	<b>199 694</b>
Current liabilities	33 581	26 567	38 153
<b>Total liabilities</b>	<b>33 581</b>	<b>26 567</b>	<b>38 153</b>
<b>Total equity and liabilities</b>	<b>571 695</b>	<b>235 127</b>	<b>237 847</b>

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

Q3 2009	Q3 2008		2009 1.1-30.9	2008 1.1-30.9	2008 1.1-31.12
181 864	219 282	<b>Equity at beginning of period</b>	199 694	259 994	259 994
914	1 368	Share-based compensation	2 742	4 103	4 483
0		De-merger of PCI Biotech/ Investment	0	-45 715	-45 715
0		Net gain de-consolidation PCI Biotech	0	45 315	45 315
355 337	-12 090	Comprehensive income	335 678	-55 136	-64 382
<b>538 114</b>	<b>208 560</b>	<b>Equity at end of period</b>	<b>538 114</b>	<b>208 560</b>	<b>199 694</b>

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

Q3 2009	Q3 2008		2009 1.1-30.9	2008 1.1-30.9	2008 1.1-31.12
355 337	-12 090	Profit/loss(-) before tax	334 630	-55 136	-64 382
384	436	Depreciation and amortisation	1 186	1 221	1 554
914	1 368	Share-based compensation	2 742	4 103	4 483
-1 721	-793	Net interests	-6 333	-6 245	-10 260
0		Write down financial assets	4 192	9 163	9 432
-366 755	-782	Changes in working capital	-381 960	-8 020	-471
215	-1 532	Other operational items	215	-62	-35
<b>-11 626</b>	<b>-13 393</b>	<b>Net cash flow from operations</b>	<b>-45 329</b>	<b>-54 977</b>	<b>-59 679</b>
1 384	-1 486	Cash flow from investments	5 747	-15 888	-12 865
-2	-4	Cash flow from capital transactions	-3	-10	-13
<b>-10 244</b>	<b>-14 883</b>	<b>Net change in cash during the period</b>	<b>-39 585</b>	<b>-70 875</b>	<b>-72 556</b>
150 556	196 461	Cash & cash equivalents at beginning of period	179 897	252 452	252 452
<b>140 312</b>	<b>181 577</b>	<b>Cash &amp; cash equivalents at end of period</b>	<b>140 312</b>	<b>181 577</b>	<b>179 897</b>



### Segment information

(Amounts in NOK 1000)	3Q 2009				% vs. PY	3Q 2008			
	Own	Partner	R&D*	Total		Own	Partner	R&D*	Total
Sales Metvix/Aktilite	5 281	8 528		13 809	-13 %	5 996	9 807		15 803
Sales Hexvix	4 716	7 746		12 461	59 %	2 620	5 206		7 826
<b>Sales revenue</b>	<b>9 996</b>	<b>16 274</b>	<b>0</b>	<b>26 270</b>	<b>11 %</b>	<b>8 617</b>	<b>15 013</b>	<b>0</b>	<b>23 629</b>
Milestone revenue	0	362 986		362 986		0	0		0
<b>Total revenues</b>	<b>9 996</b>	<b>379 260</b>	<b>0</b>	<b>389 257</b>	<b>1547 %</b>	<b>8 617</b>	<b>15 013</b>	<b>0</b>	<b>23 629</b>
Cost of goods sold	486	3 338		3 825	-16 %	493	4 079		4 572
<b>Gross profit</b>	<b>9 510</b>	<b>375 922</b>	<b>0</b>	<b>385 432</b>	<b>1922 %</b>	<b>8 124</b>	<b>10 934</b>	<b>0</b>	<b>19 057</b>
Gross profit %	95 %	99 %		99 %		94 %	73 %		81 %
Operating expenses	9 074	4 210	18 399	31 683	0 %	8 351	4 644	18 812	31 807
<b>Operating profit</b>	<b>436</b>	<b>371 712</b>	<b>-18 399</b>	<b>353 749</b>	<b>N/A</b>	<b>-227</b>	<b>6 290</b>	<b>-18 812</b>	<b>-12 750</b>
Net finance				1 588					659
<b>Profit before tax</b>	<b>436</b>	<b>371 712</b>	<b>-18 399</b>	<b>355 337</b>	<b>N/A</b>	<b>-227</b>	<b>6 290</b>	<b>-18 812</b>	<b>-12 090</b>

\* Including share of general and administrative expenses

### Segment information

(Amounts in NOK 1000)	1-3Q 2009				% vs. PY	1-3Q 2008			
	Own	Partner	R&D*	Total		Own	Partner	R&D*	Total
Sales Metvix/Aktilite	19 177	31 017		50 194	13 %	17 474	26 945		44 418
Sales Hexvix	13 065	20 973		34 038	46 %	6 822	16 487		23 309
<b>Sales revenue</b>	<b>32 243</b>	<b>51 990</b>	<b>0</b>	<b>84 232</b>	<b>24 %</b>	<b>24 296</b>	<b>43 431</b>	<b>0</b>	<b>67 727</b>
Milestone revenue	0	362 986		362 986		0	1 303		1 303
<b>Total revenues</b>	<b>32 243</b>	<b>414 976</b>	<b>0</b>	<b>447 218</b>	<b>548 %</b>	<b>24 296</b>	<b>44 734</b>	<b>0</b>	<b>69 030</b>
Cost of goods sold	1 568	11 795		13 363	2 %	1 621	11 539		13 160
<b>Gross profit</b>	<b>30 674</b>	<b>403 181</b>	<b>0</b>	<b>433 855</b>	<b>677 %</b>	<b>22 675</b>	<b>33 196</b>	<b>0</b>	<b>55 870</b>
Gross profit %	95 %	97 %		97 %		93 %	74 %		81 %
Operating expenses	29 929	14 162	56 255	100 346	-8 %	28 381	14 178	66 217	108 775
<b>Operating profit</b>	<b>746</b>	<b>389 019</b>	<b>-56 255</b>	<b>333 509</b>	<b>N/A</b>	<b>-5 707</b>	<b>19 018</b>	<b>-66 217</b>	<b>-52 905</b>
Net finance				1 121					-2 230
<b>Profit before tax</b>	<b>746</b>	<b>389 019</b>	<b>-56 255</b>	<b>334 630</b>	<b>N/A</b>	<b>-5 707</b>	<b>19 018</b>	<b>-66 217</b>	<b>-55 136</b>

\* Including share of general and administrative expenses