



Brilliance in photodynamic technology™

# Photocure ASA

Establishing a Specialty Pharma company

28 April 2010 –Results for the 1<sup>st</sup> quarter 2010

## Highlights for the first quarter 2010

(2009 figures in brackets)

- Hexvix revenues increased by 44% to NOK 14.0 million (9.7) in Q1 2010
- Total revenue of NOK 18.1 million (9.7) in the quarter, including NOK 4.1 million in milestone revenue
- Net result of NOK -13.9 million (-8.6) in Q1 2010
- Cash holding of NOK 369.9 million per 31 March 2010
- **Dermatology:**
  - Visonac: Inclusion completed in the last phase II study in January, results from study expected in May 2010
  - Allumera: Second consumer trial starts in April 2010, results expected in Q4 2010
- **Cancer:**
  - Hexvix: Reimbursement approval in Germany, triggering milestone payment of EUR 0.5 million from GE Healthcare
  - Cevira: Positive phase II results in April, efficacy and safety demonstrated for the Cevira treatment

### Key figures

<i>Figures in NOK '000</i>	<b>1st quarter 2010</b>	<b>1st quarter 2009</b>	<b>2009</b>
<b>Revenues</b>	<b>18 101</b>	<b>9 669</b>	<b>48 428</b>
<b>Gross profit</b>	<b>16 467</b>	<b>8 877</b>	<b>42 887</b>
Research and development expenses	- 19 265	- 10 543	- 78 980
Sales and marketing expenses	- 8 137	- 6 205	- 24 984
<b>Operating result (EBIT)</b>	<b>- 15 728</b>	<b>-13 493</b>	<b>- 78 952</b>
<b>Net profit/loss</b>	<b>- 13 865</b>	<b>- 8 611</b>	<b>312 382</b>
<b>Earnings per share, diluted (NOK)</b>	<b>- 0.62</b>	<b>- 0.39</b>	<b>3.46</b>

Photocure's strategy is to develop the company from a research oriented company into a Specialty Pharma company. This will be done by strengthening the commercial activity in the company with an emphasis on dermatology in the US market.



The first step of implementing the strategy was the company's divestment of Metvix/Aktilite in 2009, securing Photocure freedom to develop and commercialize new PDT based products for dermatology, as well as financial flexibility. Photocure is now implementing the next steps in the company's strategy.

The company has a strong commitment to the development of dermatology products and is preparing for commercial activities within dermatology in USA.

Within the cancer area, Photocure continues to focus on commercialization of Hexvix and development of the two new products Cevira and Lumacan through to out-licensing before phase III.

## Operational review

### Hexvix® - revenues increased by 44% to 14.0 million (9.7) in Q1 2010

<i>Figures in NOK '000</i>	<b>1<sup>st</sup> quarter 2010</b>	<b>%- change</b>	<b>1<sup>st</sup> quarter 2009</b>	<b>2009</b>
<b>Revenue – own sales of Hexvix</b>	5 817	+52.4%	3 818	16 908
<b>Revenue – partner sales of Hexvix</b>	8 143	+39.2%	5 851	29 090
<b>Total revenue</b>	<b>13 960</b>	<b>+44.4%</b>	<b>9 669</b>	<b>45 998</b>

Sales revenues for Hexvix amounted to NOK 14.0 million (9.7) in the first quarter 2010, representing an increase of 44%. Sales through GE Healthcare accounted for NOK 8.1 million (5.9), whereas Photocure's own sales in the Nordic region were NOK 5.8 million (3.8).

GE Healthcare increased the end-user sales of Hexvix by 31% to 7,303 units in the first quarter 2010 (5,572). In the Nordic region, Photocure increased sales to 1,646 units, up 75% from the first quarter 2009 (941).

Hexvix is now being sold in 21 countries in Europe by GE Healthcare and Photocure, with Germany and Denmark leading on in the introduction of Hexvix cystoscopies as a standard method for detection of bladder cancer. At the end of the first quarter 2010, more than 600 European urology clinics offer Hexvix to its bladder cancer patients.

Photocure sees a significant growth potential for Hexvix in Europe and is working together with GE Healthcare to place the equipment in more clinics, on education and to expand the use of Hexvix in all the clinics that already are equipped.

Even though Germany is a growth driver for Hexvix, the German market has been held back by limits in the temporary reimbursement system. Approval for a permanent reimbursement system (DRG code) was received in January 2010, which removes the limit and resulted in a EUR 0.5 million milestone payment from GE Healthcare in the first quarter 2010. The final DRG code issued for Hexvix expands the coverage from transurethral resections only to include also fluorescence guided transurethral resections of the bladder (TURBs).

GE Healthcare's achievement of a reimbursement code in Germany in such a short timeframe was impressive. Outside Germany, Hexvix is reimbursed in France, Spain, Denmark, Belgium and Greece.

In the Nordic region, the Hexvix market share of TURBs is now 30%, up from a market share of 23% in 2009. The growth in the number of clinics that have the necessary equipment to do Hexvix cystoscopies was 22% in the Nordic region in the first quarter of 2010 compared to the end of March 2009. The growth in usage (Hexvix kit per equipment) was 43% in the first quarter this year compared to the same period last year. These numbers are good indications for the continued growth potential in the use of Hexvix.

Hexvix received positive feedback from FDA in the fourth quarter of 2009 and announced that Hexvix can be approved in USA on certain conditions. These conditions include approval of the medical equipment used for Hexvix-cystoscopies, improved description of the reconstitution procedure, and a plan to document the repeated use of Hexvix cystoscopy. During the first quarter of 2010 the company has worked to resolve these issues and the company expects to receive a response from FDA by the end of the second quarter 2010.

### Progress in the clinical development programs

Photocure has strong platform based on photodynamic technology, Photocure Technology™, which provides a basis for the company's development projects.

	Indication	Status
<b>Hexvix®</b>	Detection of bladder cancer	Pending approval in USA
<b>Cevira™</b>	Treatment of precursors of cervical cancer	Phase I/II
<b>Lumacan™</b>	Detection of colon cancer	Phase I/II
<b>Allumera™</b>	Improved facial skin appearance	Consumer trial
<b>Visonac™</b>	Treatment of moderate to severe acne	Phase II

### Dermatology

Photocure's technology platform is very well suited for development of products that meet future needs for treatment of dermatological diseases. In addition, the technology offers opportunities to develop products for the large cosmetic market.

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

Photocure develops Visonac for treatment of moderate to severe acne. The serious side effects with existing treatments mean that there is a great medical need for new and lenient treatments for acne, especially for patients with moderate to severe acne. This also constitutes a major market opportunity as the world wide prescription market for acne is estimated to be approximately USD 3 billion, with the US as the single largest market with USD 1.65 billion.

During the first half of 2009, Photocure had meetings with regulatory authorities in Europe and USA to discuss phase II results and the outline for the phase III program.

Based on this, a multi-centre phase II study was started in USA/ Canada in the second half of 2009 with a new acne light source. 107 patients from 11 years of age were enrolled in January 2010 and the preliminary results from this study are expected in May 2010.

The results from the study in USA/ Canada, as well as discussions with the European central regulatory agency's (EMA) Paediatric Committee, will form the basis for the development of the final and joint phase III program in Europe and USA. An end-of-phase II meeting with the FDA is planned for the third quarter 2010.

**Allumera™ – A cosmetic product for improved facial skin appearance**

In 2009, Photocure started the development of a cosmetic product for the dermatology market, which is not subject to a FDA approval. The product – Allumera – is built on the reported cosmetic improvements experienced with the recently divested cancer product Metvix/Aktilite. Today the cosmetic procedure market in US alone has an estimated value of USD 4 billion. The US cosmetic market is very exposed to competition. Photocure's market research nevertheless shows that the benefits observed with Allumera offer advantages over other skin rejuvenation products on the market.

In November 2009 Photocure successfully completed a pilot consumer trial in 10 subjects showing improvement in the appearance of skin tone, pore size, elasticity and fine wrinkles. The consumer feedback was positive with regard to their improved skin appearance.

Based on this, the company started a second consumer trial approved by the ethical committee (IRB) on 22 April 2010, with results expected during the fourth quarter 2010. Photocure is working towards introducing Allumera in the US market in 2011.

**Cancer**

One of the major advantages of the Photocure Technology™ is its ability to treat and diagnose cancer precursors with a minimum of side effects. The products that are being developed meet future needs for diagnosis and treatment of the diseases before they develop into more serious stages.

**Cevira™ - Treatment of precursors for cervical cancer**

Cevira is being developed to meet the medical need among women with precursors for cervical cancer. Cervical cancer is a result of HPV virus infections, and approximately 30 million women are annually infected by an HPV virus that does not disappear within short. A prolonged infection increases the risk for development of cervical cancer. In Europe and USA approximately 7 million women are annually diagnosed with possible precursors for cervical cancer or cell changes in the cervix. There is thus a great medical need for lenient, non-surgical treatments of precursors for cervical cancer, especially for young women.

In 2009 the company completed recruitment of patients in a phase II dose study for treatment of precursors for cervical cancer (CIN 1-3) with 92 patients at University hospitals in Oslo and Hannover, Germany. Interim results from Oslo after 6 months follow-up were reported last year. The full data set, as well as data from 12 months follow-up show that the overall treatment response at varied between drug regimens, patient populations and the two centres. Drug application for 3 hours with photoactivation using a light dose of 50-100J/cm<sup>2</sup> in 24 patients with mild to moderate grade lesions (CIN1/2), showed a 58% lesion response rate across the two study sites. Moreover, the 12 month follow-up results confirm a sustained treatment response in the CIN 1/2 patient group with 63% lesion response. In addition, among the 24 patients with CIN1/2 there was a concomitant 90% HPV removal in responding patients.

Based on these encouraging results, the company initiated a placebo controlled study to confirm and compare the treatment effect versus placebo on early stage precursors (CIN1) for cervical cancer. Inclusion was finalized in February and will be followed up for 6 months. The further plan is to follow up with a new study on the same patient group to document the effect of the new treatment procedure. After finalization of this study the company will be in a better position to secure a commercial partner for Cevira.

**Lumacan™ - Diagnosis of colon cancer**

Lumacan is being developed to increase the detection rate for polyps and colon cancer through fluorescence diagnosis. Colon cancer is traditionally diagnosed through colonoscopies (visual examination) with white light. The market for colonoscopies is growing as a result of extensive patient screening programs in Europe and USA. In the US, it is estimated that approximately 14 million

colonoscopies are being carried out annually for diagnosis of colon cancer. At the same time, it is increasingly being recognized that standard white-light colonoscopy has considerable limitations when it comes to optimal detection of colon cancer.

Photocure initiated a phase I/II study with fluorescence diagnosis of colon cancer in the spring of 2009. The study is being carried out at two hospitals in Germany, and is planned to include approximately 70 patients with suspected colon cancer. Based on the strong results from earlier studies with enemas, the study was temporarily halted in the autumn of 2009 awaiting development of an improved oral formulation/procedure. After completion of exploratory clinical formulation studies designed to provide more information about the distribution of the product in the colon, the plan is to restart the phase I/II study with an improved oral formulation in the third quarter 2010.

## Financial development in the first quarter 2010

(Numbers in brackets are for the first quarter of 2009)

Photocure's divestment of Metvix/Aktilite in September 2009 changed the company's earnings profile. The 2009 accounts are adjusted for discontinued operations.

The sales revenues for the first quarter amounted to NOK 14.0 million (9.7). In addition, Photocure received NOK 4.1 million (0.0) in milestone revenue from GE Healthcare in the first quarter, due to the approval of reimbursement for Hexvix in Germany in January 2010.

Other income amounted to NOK 5.6 million (0.6) in the first quarter. This includes NOK 3.0 in deferred revenue from the sales of Metvix/Aktilite, sale of API to Galderma of NOK 0.4 million, and NOK 0.6 million in SkatteFunn.

Total research & development (R&D) costs increased to NOK 19.3 million in the first quarter (10.5), as a result of the announced increased focus on development projects. Dermatology R&D related to Visonac and Allumera accounted for NOK 8.1 million, and Cancer R&D related to Hexvix, Lumacan and Cevira for NOK 10.7 million. NOK 0.5 million was spent on explorative research.

Marketing and sales costs increased to NOK 8.1 million in the first quarter (6.2). This consists of NOK 5.4 million for Hexvix (own sales and partner sales), and NOK 2.7 million for dermatology related to preparations for the planned launch of Allumera in the US.

The company had an operating loss of NOK -15.7 million (-13.5) in the first quarter 2010.

Photocure is the largest owner with 19.35% of the shares in PCI Biotech Holding ASA (PCI Biotech). The book value of the shareholding increased from NOK 11.5 million at 31 December 2009 to NOK 40.9 million at 31 March 2010, as the fair value of the PCI Biotech share increased from NOK 11.00 to NOK 39.00 per share. Photocure's shares in PCI Biotech are classified as available for sale and fair value changes has to be recognised through other comprehensive income unless a write-down due to an impairment has occurred.

Net financial items were NOK 1.9 million in the quarter (-2.9). Net financial loss in the first quarter 2009 included a write-down of the shares in PCI Biotech of NOK 4.2 million.

Photocure thus recorded a net loss of NOK -13.9 million in the quarter (-8.6).

Cash and cash equivalents were NOK 369.9 million at the end of first quarter compared, to NOK 403.5 million at the end of 2009. Shareholders' equity was NOK 424.3 million, or 94%, at the end of first quarter 2010. This is an increase from NOK 415.8 million at the end of 2009.

Photocure bought 235,450 shares under its share repurchase program in the first quarter, for an average of NOK 45.97 per share. Photocure sold 112,019 own shares to employees in the first quarter, and owns 528,303 or 2.4% of the outstanding shares per 27 April 2010. Net cash cost for own shares in the period is NOK 8.1 million.

## Subsequent events after the end of the quarter

On 21 April 2010, Photocure announced that a European expert panel recommends the use of Hexvix cystoscopy in the diagnosis and follow up of non-muscle-invasive bladder cancer. The company expects that the recommendation from the consensus group will make the use of Hexvix-guided fluorescence cystoscopy more unison in Europe.

On 23 April 2010, PCI Biotech Holding ASA proposed a share capital increase of NOK 90 million. The purpose of the rights issue is to strengthen the equity to enable the company to complete the planned clinical development studies within selected cancer indications. The rights issue is subject to approval by an extraordinary general meeting in PCI Biotech. Photocure will participate in the guarantee consortium with a 20% share.

## Outlook

Photocure's strategy is to develop the company from a research based organization into a Specialty Pharma company. This will be done through a strengthening of the commercial activity in the company, with a special emphasis on dermatology in USA.

Photocure will work to resolve the outstanding requirements from the FDA to get the final approval for Hexvix in the US. An approval of Hexvix in the US will trigger a milestone payment of € 10 million from GE Healthcare.

In research and development the main task will be to carry out clinical studies and secure the progress in development of new therapies and treatment procedures within the core areas in dermatology and cancer. The company expects results from a multi-centre phase II study with Visonac in May, and to restart the phase II study with oral formulation with Lumacan in October.

Sales of Hexvix in Europe are expected to grow 30%+ in 2010, depending on the uptake in key markets.

Total expenses for 2010 are estimated to increase compared to 2009, in particular because of the increased activities in the Dermatology field and the continuous development in the Cancer field.

To optimise the value of the cancer portfolio the company is working to out-license Cevira and Lumacan before start of phase III of the clinical program.

The Board of Directors and CEO  
Photocure ASA

Oslo, 28 April, 2010

## Statement of comprehensive income

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

	2010 1.1-31.3	2009 1.1-31.3	2009 1.1-31.12
Sales revenues	13 960	9 669	48 428
Signing fee and milestone revenues	4 140	0	0
<b>Total revenues</b>	<b>18 101</b>	<b>9 669</b>	<b>48 428</b>
Cost of products sold	-1 634	-792	-5 541
<b>Gross profit</b>	<b>16 467</b>	<b>8 877</b>	<b>42 887</b>
Other income	5 910	562	11 652
Indirect manufacturing expenses	-1 988	-1 630	-9 451
Research and development expenses	-19 265	-10 543	-78 980
Marketing and sales expenses	-8 137	-6 205	-24 984
Business development and administrative expenses	-8 715	-4 555	-20 076
<b>Operating profit/loss(-)</b>	<b>-15 728</b>	<b>-13 493</b>	<b>-78 952</b>
Financial income	2 757	3 998	13 551
Financial expenses	-894	-6 875	-11 100
<b>Net financial profit/loss(-)</b>	<b>1 862</b>	<b>-2 877</b>	<b>2 451</b>
<b>Profit/loss(-) before tax</b>	<b>-13 865</b>	<b>-16 370</b>	<b>-76 501</b>
Tax expenses	0	0	0
Discontinued operations (1)	0	7 759	388 883
<b>Net profit/loss(-)</b>	<b>-13 865</b>	<b>-8 611</b>	<b>312 382</b>
Other comprehensive income	29 344	0	4 192
<b>Comprehensive income</b>	<b>15 479</b>	<b>-8 611</b>	<b>316 574</b>
Net profit/loss(-) per share, undiluted (2)	-0.63	-0.39	3.46
Net profit/loss(-) per share, diluted (3)	-0.62	-0.39	3.46

(1) The Metvix/Aktillite business was sold in 3Q09 and related revenues &amp; expenses in 1Q09 are reclassified to Discontinued operations

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

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

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

	31.03.2010	31.03.2009	31.12.2009
<b>Non-current assets</b>			
Intangible assets, software	335	511	365
Machinery & equipment	1 886	2 483	1 772
Other investments (1)	46 952	7 336	14 585
<b>Total non-current assets</b>	<b>49 172</b>	<b>10 330</b>	<b>16 722</b>
<b>Current assets</b>			
Inventory	13 922	12 300	13 826
Receivables	19 025	15 242	22 811
Cash & cash equivalents	369 912	161 872	403 502
<b>Total current assets</b>	<b>402 858</b>	<b>189 415</b>	<b>440 140</b>
<b>Total assets</b>	<b>452 031</b>	<b>199 745</b>	<b>456 862</b>
<b>Equity and liabilities</b>			
<b>Equity</b>			
Share capital	11 047	11 047	11 047
Other paid-in capital	169 198	189 562	176 112
Retained earnings	244 102	-29 658	228 624
<b>Shareholders' equity</b>	<b>424 347</b>	<b>170 950</b>	<b>415 783</b>
<b>Long-term liabilities</b>			
Other non-current liabilities	420	0	340
<b>Total long-term liabilities</b>	<b>420</b>	<b>0</b>	<b>340</b>
Current liabilities	27 263	28 795	40 739
<b>Total liabilities</b>	<b>27 684</b>	<b>28 795</b>	<b>41 079</b>
<b>Total equity and liabilities</b>	<b>452 031</b>	<b>199 745</b>	<b>456 862</b>

(1) Including shares in PCI Biotech Holding ASA at market value kNOK 40.872 as of 31.3.10 (kNOK 11.528 as of 31.12.09)

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

	<b>2010</b>	<b>2009</b>	<b>2009</b>
	<b>1.1-31.3</b>	<b>1.1-31.3</b>	<b>1.1.-31.12</b>
<b>Equity at beginning of period</b>	<b>415 783</b>	<b>199 694</b>	<b>199 694</b>
Share buy back, net	-8 109	0	-15 989
Dividend	0	0	-87 950
Share-based compensation	1 195	914	3 454
Comprehensive income	15 479	-8 611	316 574
<b>Equity at end of period</b>	<b>424 347</b>	<b>191 997</b>	<b>415 783</b>

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

	<b>2010</b>	<b>2009</b>	<b>2009</b>
	<b>1.1-31.3</b>	<b>1.1-31.3</b>	<b>1.1.-31.12</b>
Profit/loss(-) before tax	-13 865	-8 611	312 382
Depreciation and amortisation	275	398	1 451
Share-based compensation	1 195	914	3 454
Net interests	-2 398	-2 510	-9 258
Write down financial assets	0	4 192	4 192
Changes in working capital	-9 785	-14 760	7 899
Other operational items	-3 063	-1	-2 674
<b>Net cash flow from operations</b>	<b>-27 642</b>	<b>-20 378</b>	<b>317 445</b>
Cash flow from investments	2 160	2 353	10 104
Cash flow from capital transactions	-8 109	0	-103 944
<b>Net change in cash during the period</b>	<b>-33 591</b>	<b>-18 025</b>	<b>223 605</b>
Cash & cash equivalents at beginning of period	403 502	179 897	179 897
<b>Cash &amp; cash equivalents at end of period</b>	<b>369 912</b>	<b>161 872</b>	<b>403 502</b>

**Segment information**

<b>1Q 2010</b> (Amounts in NOK 1000)						
	<b>Cancer</b>			<b>Derm.(2)</b>	<b>Total</b>	<b>% vs. PY</b>
	<b>Own</b>	<b>Partner</b>	<b>R&amp;D(1)</b>			
Sales Hexvix	5 817	8 143	0	0	13 960	44 %
Cost of goods sold	-363	-1 271			-1 634	106 %
<b>Gross profit</b>	<b>5 454</b>	<b>6 872</b>	<b>0</b>	<b>0</b>	<b>12 326</b>	<b>39 %</b>
Gross profit %	94 %	84 %	0	0	88 %	
Milestone revenues	0	4 140	0	0	4 140	
MAL/Metvix/Aktelite revenues (3)	0	0	0	0	4 088	
Operating expenses	-5 140	-3 291	-12 034	-15 817	-36 282	62 %
<b>Operating profit</b>	<b>314</b>	<b>7 721</b>	<b>-12 034</b>	<b>-15 817</b>	<b>-15 727</b>	
Net finance					1 862	
<b>Profit before tax</b>	<b>314</b>	<b>7 721</b>	<b>-12 034</b>	<b>-15 817</b>	<b>-13 865</b>	
<b>1Q 2009</b> (Amounts in NOK 1000)						
	<b>Cancer</b>			<b>Derm. R&amp;D</b>	<b>Total</b>	
	<b>Own</b>	<b>Partner</b>	<b>R&amp;D(1)</b>			
Sales Hexvix	3 818	5 851	0	0	9 669	
Cost of goods sold	-160	-632	0	0	-792	
<b>Gross profit</b>	<b>3 658</b>	<b>5 220</b>	<b>0</b>	<b>0</b>	<b>8 877</b>	
Gross profit %	96 %	89 %			92 %	
Discontinued operations	0	0	0	0	7 759	
Operating expenses	-5 479	-2 326	-13 016	-1 550	-22 371	
<b>Operating profit</b>	<b>-1 821</b>	<b>2 893</b>	<b>-13 016</b>	<b>-1 550</b>	<b>-5 735</b>	
Net finance					-2 877	
<b>Profit before tax</b>	<b>-1 821</b>	<b>2 893</b>	<b>-13 016</b>	<b>-1 550</b>	<b>-8 612</b>	

(1) Including share of general and administrative expenses

(2) R&D Visonac/Allumera, Business development and Admin expenses

(3) Deferred revenue from Metvix divestment, sale of MAL, returns and reimbursement of Metvix

**For more information, please contact:**

Kjetil Hestdal, President and CEO

Mobile: +47 913 19 535

E-mail: [kh@photocure.no](mailto:kh@photocure.no)

Christian Fekete, CFO

Mobile: +47 916 42 938

E-mail: [cf@photocure.no](mailto:cf@photocure.no)

Photocure ASA  
 Hoffsvæien 48  
 NO – 0377 Oslo  
 Norway

Telephone: +47 22 06 22 10

Fax: +47 22 06 22 18