



**Brilliance in photodynamic technology**

Results for the first quarter 2011

# Photocure ASA

The world leader in photodynamic technology

27 April 2011

## Highlights for the first quarter 2011

(Q1 2010 figures in brackets)

- Hexvix<sup>®</sup> sales to end users (units) up by 21% vs. first quarter 2010
- Sales revenues of up by 21% to NOK 20.9 million (NOK 17.3 million)
- Operating loss of NOK 17.5 million (NOK 15.7 million)
- Cash & cash equivalents of NOK 362.0 million at 31 March 2011
- Positive final results from consumer trial for Allumera<sup>™</sup>; on track for US launch in June
- Solid clinical results from six months follow up study from Cevira<sup>®</sup>
- Publication in prestigious *British Journal of Urology* of Hexvix data on reducing the risk of bladder cancer recurrence

### Key figures

<b>NOK million</b> (group – unaudited-adjusted)	<b>Q111</b>	<b>Q110</b>	<b>2010</b>
Sales revenues	20.9	17.3	70.5
Signing fee/ milestone rev	0	4.1	106.8
<b>Total revenues</b>	<b>20.9</b>	<b>21.4</b>	<b>177.4</b>
<b>Gross profit</b>	<b>16.7</b>	<b>19.8</b>	<b>168.2</b>
R&D expenses	(13.0)	(19.3)	(90.2)
<b>Operating profit</b>	<b>(17.5)</b>	<b>(15.7)</b>	<b>7.5</b>
<b>Net profit</b>	<b>(15.9)</b>	<b>(13.9)</b>	<b>18.1</b>
EPS, diluted (NOK)	(0.74)	(0.62)	0.83

## Strategy

Photocure's strategy is to build a specialty pharma company by maximising the potential of its strong platform of intellectual property in photodynamic therapy within the two disease areas dermatology and cancer.

Photocure develops innovative dermatology therapies and cosmetics, cancer diagnostics and therapies, and markets and sells these products through its own sales force and in partnerships with other companies.

Within dermatology, Photocure is developing Allumera<sup>®</sup>, a breakthrough cosmetic treatment formulated to improve the skin's appearance, and Visonac<sup>®</sup> for treating moderate to severe acne.

Photocure has established its own commercial platform in the US and plans to launch Allumera during second quarter 2011.

In cancer, Photocure's strategy is to out-license its products before phase III development, and retain commercial rights in some regions. It has one marketed product, Hexvix®/Cysview™ for the detection of bladder cancer. Photocure is focused on expanding sales of Hexvix. Lumacan®, which is in phase I/II development for the detection of colon cancer, was licensed to Salix Pharmaceuticals ("Salix") in October 2010. Cevira® is in phase II development as the first non-surgical therapeutic option for treating cervical HPV infection and precancerous lesions of the cervix.

## Operational review

Photocure operates within two disease areas; Dermatology and Cancer. The company has one product on the market - Hexvix, for the detection of bladder cancer and a pipeline of products in development.

Hexvix was launched in Europe in 2006. Photocure has a worldwide licensing agreement with GE Healthcare for Hexvix. Photocure has retained the rights to the Nordic region where it markets and sells Hexvix through its own sales organisation.

### Hexvix

#### Revenues from sales of Hexvix

<i>figures in NOK '000</i>	Q1 2011	Change	Q1 2010	2010
Own sales	5 690	-2%	5 817	19 533
Partner sales	9 071	11%	8 143	38 085
<b>Total revenue</b>	<b>14 761</b>	<b>6%</b>	<b>13 960</b>	<b>57 618</b>

Total sales revenues for Hexvix amounted to NOK 14.8 million (NOK 14.0 million) in the first quarter 2011. Sales through GE Healthcare accounted for NOK 9.1 million (NOK 8.1 million). Sales in units from GE Healthcare to end-users increased by 25% from 7,303 units in first quarter 2010 to 9,122 units in the first quarter 2011. Photocure's own sales in the Nordic region were NOK 5.7 million (NOK 5.9 million). However, the unit sales in the Nordic region increased by 5% from 1,646 in the first quarter 2010 to 1,729 units in the first quarter 2011.

There are a number of factors driving Hexvix sales, which provides confidence for continued growth in Europe. The key factor is GE Healthcare's allocation of resources to marketing and sales of Hexvix. Photocure has reached a approximately 31% marketshare of Hexvix in the Nordic region while GE Healthcare has reached approximately 10% in the rest of Europe. The Nordic marketshare demonstrates the potential of Hexvix in markets with limited market penetration today.

A second article on the impact of Hexvix' ability to reduce bladder cancer recurrence was published in the prestigious *British Journal of Urology* in March 2011. The article documented that Hexvix-guided fluorescence cystoscopy, as an adjunct to conventional white-light cystoscopy, improves the detection of bladder cancer and reduces the rate of early tumour recurrence, compared with white-light cystoscopy alone.



Hexvix was approved under the tradename Cysview in the US in May 2010. GE Healthcare, responsible for marketing and sales of Cysview in the US, and Karl Storz, responsible for marketing and sales of blue light cystoscopy equipment in the US, are establishing training centres for urologists.

Karl Storz' has applied to the FDA for an amendment to the PMA application in order to approve the updated version of the scopes to a version already on the market in Europe. The application is still under review by the FDA . Photocure had expected a higher level of activities in the marketing and sales of Cysview in the first quarter than has been the case.

## Progress in the clinical development programs

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

Dermatology	Indication/Claim	Status
Allumera	Improved facial skin appearance	Preparing to launch in US
Visonac	Treatment of moderate to severe acne	Phase II
<b>Cancer</b>		
Hexvix /Cysview	Detection of bladder cancer	Approved in EU/US
Cevira	Treatment of HPV/precancerous cervix lesions	Phase II
Lumacan	Detection of colon cancer	Licensed to Salix

## Dermatology

Photocure's photodynamic technology is very well suited for the development of products that meet the needs to treat dermatological diseases. PDT is an established procedure in the dermatology field, and Photocure has been a leader in developing effective PDT products to serve that market. In addition, the technology offers opportunities to develop products for the large cosmetic and skin revitalisation market.

In 2010, Photocure established a US subsidiary, Photocure Inc., which has started to build its own marketing and sales force in dermatology in the US.

### Allumera – A cosmetic product for improved facial skin appearance

Photocure started the development of Allumera, a breakthrough cosmetic treatment formulated to improve the skin's appearance, in 2009. In February 2011, Photocure announced positive results from its consumer trial, the RevitAll study. The study was performed with a standard cosmetic protocol and designed to confirm if treatment with Allumera improves skin appearance, when compared to exposure by light alone. The study also looked into longevity of results.

The results from the RevitAll study provide a solid foundation for Photocure to commercialize Allumera in the US. The results from this study showed that Allumera significantly improved the appearance of the skin including significant improvements in appearance of pores, skin firmness and suppleness compared to the control group. Photocure will launch the new dermatology cosmetic Allumera in the US market in the beginning of June 2011.

### Visonac – treatment of moderate to severe acne



Following a market research study on the positioning of Visonac, Photocure sees significant potential for Visonac in treating acne. It plans to carry out a multicenter phase IIb study in the US, starting in the second quarter 2011. This study will include approx. 150 acne patients on 12-15 sites in the US. Primary endpoints are reduction in acne lesions. Photocure plans to report the results from this study in the second half of 2012.

## **Cancer**

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

### Cevira - Treatment of precursors for cervical cancer

Photocure is developing Cevira as the first non-surgical therapeutic option for treating cervical HPV infection and precancerous lesions of the cervix. Cevira is a photodynamic therapy that combines a drug formulation with a medical device and offers the potential for an easy, quick and safe treatment procedure for patients with mild cervical abnormalities.

Cervical HPV-induced lesions affect seven million women in Europe and the US each year. Current treatment of precancerous lesions involves invasive surgical procedures to remove the precancerous lesions, which can result in the unnecessary removal of normal cervical tissue. Besides discomfort and recovery time, this can affect the patient's ability to carry a child full-term, impact fertility and increase the risk of post-surgical infections. For a large number of patients with persistent HPV infections and low-grade cellular abnormalities, there are currently no non-surgical treatment alternatives available and frequent follow up visits to avoid further disease progression causes patient anxiety and adds to the burden for the health care system.

In January 2011, Photocure announced final six month follow up results from its phase IIa study with Cevira in patients with low-grade precancerous lesions of the cervix. The results showed a complete removal of intracervical lesions in over 50% of patients enrolled in the trial.

To date, more than 200 patients have successfully received Cevira. A recent market research survey among US gynaecologists and payers conducted by Photocure confirms the market need and opportunity for Cevira in patients with low and moderate grade cervical lesions. The FDA has granted permission for Photocure to start a phase II clinical study in the US with Cevira in women with low-grade precancerous lesions of the cervix using the new intravaginal combination product. This study is planned to start in second quarter 2011. Photocure plans to report the results from the study in the second half of 2012.

### Lumacan - Diagnosis of colon cancer

Photocure signed a global agreement for development and commercialisation of Lumacan with Salix (NASDAQ:SLXP), a US specialty pharmaceutical company focused on gastrointestinal disease, in October 2010. Lumacan is being developed to increase the detection rate for polyps and colon cancer.

Colon cancer is traditionally diagnosed through colonoscopies (visual examination) with white light. However, it is increasingly being recognised that standard white-light colonoscopy has considerable limitations. Lumacan is being developed for use in conjunction with standard white light colonoscopy diagnosis.

Salix provided an update in March 2011 on its development plans for Lumacan. It is working on the formulation in 2011 and plans to start a phase II study in 2012. This will be a major milestone in the development of Lumacan.

Under the agreement, Salix obtained an exclusive worldwide license to Lumacan excluding the Nordic region. Salix will control and cover further development, registration and commercialisation costs for Lumacan worldwide. Photocure is entitled to receive milestone payments totalling up to USD 126.5 million. In addition to the milestones, Salix will pay Photocure royalties on net sales in the US and a percentage of all Salix sublicense revenue outside the US.

## Financial review

(Numbers in brackets are for the corresponding period in 2010)

Sales revenues were NOK 20.9 million (17.3 million) in the first quarter 2011, representing an increase of 21%. Sales revenues include royalties and sale of Hexvix kits to GE Healthcare, sale of Hexvix to the Nordic wholesalers, in addition to royalty and deferred revenues from Galderma. Sales revenues include NOK 3.1 million related to sales of active pharmaceutical ingredients to Galderma and Salix.

Cost of goods sold was NOK 4.2 million (NOK 1.6 million) in the first quarter 2011. The increase from first quarter 2010 is related to the sale of active pharmaceutical ingredients to Galderma and Salix.

Research and development (R&D) expenses amounted to NOK 13.0 million (19.3 million) for the quarter. The reduction compared to last year is mainly related to lower activities in clinical programs for Cevira and Visonac and no costs related to development of Lumacan. R&D costs related to development of Lumacan are now taken over by Salix. However, R&D expenses are expected to increase over the coming quarters in line with the start-up of phase II studies for Cevira and Visonac.

Marketing and sales (M&S) expenses increased to NOK 10.7 million (8.1 million) in the first quarter 2011, mainly due to increased activities in dermatology, related to the establishment of a marketing and sales organization in the US. M&S expenses are expected to increase over the next quarters to reflect a sales organization of 12-15 people in the US.

Operating loss was NOK 17.5 million (15.7 million) in the first quarter 2011.

Photocure is the largest shareholder in PCI Biotech Holding ASA (PCI Biotech) with 19.35% of the shares. The book value of the shareholding increased from NOK 69.9 million at 31 December 2010 to NOK 71.9 million at 31 March 2011, as the price of the PCI Biotech share increased from NOK 47.10 to NOK 48.50 per share.

Total equity and liabilities for Photocure was NOK 486.0 million at the end of the first quarter 2011 compared to NOK 513.8 million at the end of 2010.

Liquid funds amounted to NOK 362.0 million at the end of the first quarter 2011, down from NOK 389.2 million at the end of 2010, due to net cash flow from operations of NOK -22.7 million and NOK -5.5 million related to repurchase of own shares during the first quarter.

Shareholders' equity was NOK 441.9 million, or 91% at the end of first quarter 2011, down from NOK 458.9 million at the end of 2010.

Photocure bought 185,317 shares under its share repurchase program in the first quarter 2011, for an average of NOK 47.31 per share, and sold 150,773 shares to employees in the same period, resulting in an ownership of 730,199 or 3.3 % of the outstanding shares per 31 March 2011. The total number of registered shares was 22,093,301 at the end of first quarter 2011.

## Outlook

Photocure has a strong focus on increasing the sales of Hexvix in Europe and to support the launch of Cysview in the US market.

The Company believes Hexvix is still in an early phase of its lifecycle and see a continued healthy growth potential for the product, through more use at existing centres in Europe, more new centres, and in new geographical markets such as the US.

Photocure will launch the new dermatology cosmetic Allumera in the US market in the beginning of June 2011.

During the second quarter 2011 Photocure plans to start phase II studies for both Cevira and Visonac.

The Board of Directors  
Photocure ASA

Oslo, 27 April, 2011

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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 2010.

## Photocure ASA – Statement of comprehensive income



Q1 2011	Q1 2010		2011 1.1-31.3	2010 1.1-31.3	2010 1.1-31.12
20 940	17 343	Sales revenues (1)	20 940	17 343	70 517
0	4 140	Signing fee and milestone revenues	0	4 140	106 840
<b>20 940</b>	<b>21 483</b>	<b>Total revenues</b>	<b>20 940</b>	<b>21 483</b>	<b>177 357</b>
-4 221	-1 634	Cost of goods sold	-4 221	-1 634	-9 124
<b>16 719</b>	<b>19 849</b>	<b>Gross profit</b>	<b>16 719</b>	<b>19 849</b>	<b>168 233</b>
547	2 527	Other income (1)	547	2 527	7 392
-2 258	-1 988	Indirect manufacturing expenses	-2 258	-1 988	-8 675
-13 028	-19 265	Research and development expenses	-13 028	-19 265	-90 167
-10 681	-8 137	Marketing and sales expenses	-10 681	-8 137	-35 401
-8 814	-8 715	Business development and administrative expenses	-8 814	-8 715	-33 861
<b>-17 515</b>	<b>-15 728</b>	<b>Operating profit/loss(-)</b>	<b>-17 515</b>	<b>-15 728</b>	<b>7 521</b>
2 816	2 757	Financial income	2 816	2 757	15 149
-1 232	-894	Financial expenses	-1 232	-894	-4 578
<b>1 584</b>	<b>1 862</b>	<b>Net financial profit/loss(-)</b>	<b>1 584</b>	<b>1 862</b>	<b>10 571</b>
<b>-15 931</b>	<b>-13 865</b>	<b>Profit/loss(-) before tax</b>	<b>-15 931</b>	<b>-13 865</b>	<b>18 092</b>
0	0	Tax expenses	0	0	0
<b>-15 931</b>	<b>-13 865</b>	<b>Net profit/loss(-)</b>	<b>-15 931</b>	<b>-13 865</b>	<b>18 092</b>
2 077	29 344	Other comprehensive income	2 077	29 344	40 923
<b>-13 854</b>	<b>15 479</b>	<b>Comprehensive income</b>	<b>-13 854</b>	<b>15 479</b>	<b>59 015</b>
-0.75	-0.63	Net profit/loss(-) per share, undiluted (2)	-0.75	-0.63	0.84
-0.74	-0.62	Net profit/loss(-) per share, diluted (3)	-0.74	-0.62	0.83

(1) Q1/2010 Reclassified from Other income to Sales revenues by 3.383 kNOK

(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.



## Photocure ASA – Balance sheet

	31.03.2011	31.03.2010	31.12.2010
<b>Non-current assets</b>			
Machinery & equipment	3 181	2 221	1 929
Other investments (1)	89 374	46 952	84 263
<b>Total non-current assets</b>	<b>92 555</b>	<b>49 172</b>	<b>86 192</b>
<b>Current assets</b>			
Inventory	14 882	13 922	18 191
Receivables	16 608	19 025	20 218
Cash & cash equivalents	361 985	369 912	389 241
<b>Total current assets</b>	<b>393 475</b>	<b>402 858</b>	<b>427 651</b>
<b>Total assets</b>	<b>486 030</b>	<b>452 031</b>	<b>513 842</b>
<b>Equity and liabilities</b>			
<b>Equity</b>			
Share capital	11 047	11 047	11 047
Other paid-in capital	69 135	81 249	72 145
Retained earnings	361 689	332 052	375 663
<b>Shareholders' equity</b>	<b>441 871</b>	<b>424 347</b>	<b>458 854</b>
<b>Long-term liabilities</b>			
Other non-current liabilities	783	420	690
<b>Total long-term liabilities</b>	<b>783</b>	<b>420</b>	<b>690</b>
Current liabilities	43 376	27 263	54 298
<b>Total liabilities</b>	<b>44 159</b>	<b>27 683</b>	<b>54 988</b>
<b>Total equity and liabilities</b>	<b>486 030</b>	<b>452 031</b>	<b>513 842</b>

(1) Including shares in PCI Biotech Holding ASA at market value kNOK 71 942 as of 31.3.11 (kNOK 40 872 as of 31.3.10)

## Photocure ASA – Changes in equity

(all amounts in NOK 1,000)

Q1 2011	Q1 2010		2011 1.1-31.3	2010 1.1-31.3	2010 1.1.-31.12
<b>458 854</b>	<b>415 783</b>	<b>Equity at beginning of period</b>	<b>458 854</b>	<b>415 783</b>	<b>415 783</b>
-5 506	-8 109	Share buy back, net	-5 506	-8 109	-21 497
2 076	1 195	Share-based compensation	2 076	1 195	5 480
300		Currency translation	300		73
-13 854	15 479	Comprehensive income	-13 854	15 479	59 015
<b>441 871</b>	<b>424 347</b>	<b>Equity at end of period</b>	<b>441 871</b>	<b>424 347</b>	<b>458 854</b>

## Photocure ASA – Cash flow Statement

(all amounts in NOK 1,000)

Q1 2011	Q1 2010		2011 1.1-31.3	2010 1.1-31.3	2010 1.1.-31.12
-15 931	-13 865	Profit/loss(-) before tax	-15 931	-13 865	18 092
271	275	Depreciation and amortisation	271	275	1 316
2 076	1 195	Share-based compensation	2 076	1 195	5 480
-2 079	-2 398	Net interests	-2 079	-2 398	-10 123
-4 272	-9 785	Changes in working capital	-4 272	-9 689	11 787
-2 784	-3 063	Other operational items	-2 784	-3 159	-10 956
<b>-22 719</b>	<b>-27 642</b>	<b>Net cash flow from operations</b>	<b>-22 719</b>	<b>-27 642</b>	<b>15 596</b>
970	2 160	Cash flow from investments	970	2 160	-8 346
-5 508	-8 109	Cash flow from capital transactions	-5 508	-8 109	-21 512
<b>-27 257</b>	<b>-33 591</b>	<b>Net change in cash during the period</b>	<b>-27 257</b>	<b>-33 591</b>	<b>-14 262</b>
389 241	403 502	Cash & cash equivalents at beginning of period	389 241	403 502	403 502
<b>361 985</b>	<b>369 912</b>	<b>Cash &amp; cash equivalents at end of period</b>	<b>361 985</b>	<b>369 912</b>	<b>389 241</b>

**Photocure ASA – Segment information**

1Q 2011 (Amounts in NOK 1000)	Cancer			Derm.(3)	Total	% vs. PY
	Own	Partner	R&D (2)			
Sales Revenues (1)	5 690	9 071	181	5 998	20 940	21 %
Milestone revenues					0	
Cost of goods sold	-384	-1 050	-158	-2 629	-4 221	158 %
<b>Gross profit</b>	<b>5 306</b>	<b>8 021</b>	<b>23</b>	<b>3 369</b>	<b>16 719</b>	<b>-16 %</b>
Gross profit %	93 %	88 %	13 %	56 %	80 %	
Operating expenses	-4 560	-5 598	-7 597	-16 479	-34 234	-4 %
<b>Operating profit/loss (-)</b>	<b>746</b>	<b>2 423</b>	<b>-7 574</b>	<b>-13 110</b>	<b>-17 515</b>	<b>11 %</b>
Net finance					1 584	
<b>Profit/loss (-) before tax</b>					<b>-15 931</b>	<b>15 %</b>
1Q 2010 (Amounts in NOK 1000)						
	Cancer			Derm.(3)	Total	
	Own	Partner	R&D (2)			
Sales Revenues (1)	5 817	8 143	0	3 383	17 343	
Milestone revenues		4 140			4 140	
Cost of goods sold	-363	-1 271	0		-1 634	
<b>Gross profit</b>	<b>5 454</b>	<b>11 012</b>	<b>0</b>	<b>3 383</b>	<b>19 849</b>	
Gross profit %	94 %	135 %		100 %	114 %	
Operating expenses	-5 140	-3 291	-12 034	-15 112	-35 577	
<b>Operating profit/loss (-)</b>	<b>314</b>	<b>7 721</b>	<b>-12 034</b>	<b>-11 729</b>	<b>-15 728</b>	
Net finance					1 862	
<b>Profit/loss (-) before tax</b>					<b>-13 865</b>	

(1) Including deferred revenue from Metvix divestment

(2) Including share of administrative expenses

(3) R&D Visonac/Allumera and share administrative expenses

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