



# First Quarter Report 2009

## Highlights

- Sales revenues increased 36% to NOK 29.1 million (NOK 21.4 million)
- Operating result improved by NOK 16.7 million to NOK -5.7 million (NOK -22.5 million)
- Liquid funds amounted to NOK 161.9 million at the end of the period.
- Cevira™ - patient recruitment started in phase I/II study for photodynamic treatment of precancerous lesions of the cervix.
- Lumacan™ - patient recruitment started in phase I/II study for photodynamic detection of colon cancer using an oral capsule as administration of the drug.
- Photocure won a patent case extending the patent on Metvixia™ in the USA until July 2018.

### **Hexvix® – sales revenue increased by 32%**

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. As of today, Hexvix is sold in 19 countries in Europe, with Germany and Denmark being the most advanced markets.

As a result of this increased activity and the growing acceptance of our photodynamic approach, sales revenue from Hexvix increased by 32 % in the first quarter of 2009 to NOK 9.7 million compared to NOK 7.3 million in the first quarter of 2008. Sales revenue from GE Healthcare was NOK 5.9 million in the first quarter of 2009, compared to NOK 5.1 million in the first quarter 2008 in spite of a reduction of inventory levels at GE Healthcare. Hexvix sales in units from GE Healthcare increased with 61% from 3.463 in the first quarter 2008 to 5.572 units in the first quarter 2009. Sales of Hexvix by Photocure in the Nordic region was NOK 3.8 million in the first quarter of 2009, compared to NOK 2.2 million in the first quarter 2008. Hexvix sales in units from own sales increased with 55% from 652 in the first quarter 2008 to 1.009 units in the first quarter 2009.

Hexvix received excellent attention at the recent annual congress of the European Association of Urology in Stockholm, Sweden (March 17-21, 2009) at which data on the favourable recurrence of Hexvix was presented for the first time.

### **Metvix®/Aktilite® – sales revenue increased by 38 %**

Sales revenue from Metvix/Aktilite, for the photodynamic treatment (PDT) of cancerous and precancerous skin lesions, in the first quarter of 2009 was NOK 19.4 million compared to NOK 14.1 million in the first quarter of 2008, an increase of 38 %. Sales in the Nordic region by Photocure increased 43 % to NOK 8.1 million in the first quarter of 2009 compared to the same period in 2008, mainly as a result of a more experienced commercial operation in addition to a reduction in inventory levels in Norway/Sweden in the first quarter of 2008. Metvix sales in units from own sales increased with 17% from 3.405 in the first quarter of 2008 to 3.967 units in the first quarter of 2009. Sales revenue from Galderma, our commercial partner for Metvix/Aktilite outside the Nordic region, increased by 34 % to NOK 11.3 million for the period, compared to NOK 8.5 million in the first quarter of 2008 despite the slow sales development in USA. These increased revenues were due to higher sales of Aktilite lamps, 64 lamps in the first quarter of 2009 compared to 41 lamps in the



first quarter of 2008, and sales of Metvix tubes itself increased 10 % to 15.604 units in the first quarter of 2009.

Photocure received marketing authorization from the Canadian Health Authorities for Metvix/Aktilite in April 2009. Metvix® in combination with Aktilite® CL128 has been approved by Health Canada for the treatment of actinic keratosis (pre-cancerous skin lesions) and superficial basal cell carcinoma (sBCC skin cancer).

### **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 first 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 and using the light-activated therapeutic compound methyl aminolevulinate.

Photocure had meetings with regulatory authorities in Europe and the US in the first quarter 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. To reduce the risk and optimize the phase III program, FDA recommended to collect more data in a younger population down to 9-12 years with the new acne lamp. The EU regulatory authorities supported start of a phase III based on the existing clinical data. Photocure is currently seeking additional regulatory advice from European member states on design of the phase III program before initiation of the phase III program.

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

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

Patient recruitment started in the first quarter of 2009 in a new phase I/II clinical proof-of-concept study in 70 patients with low grade dysplasia (CIN1). 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.

In 2008, the Cevira project was awarded NOK 4.3 million over 3 years from 2009. The Research Council of Norway increased the grant for the Cevira project by NOK 1.25 million in April 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 new 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 and the results will be available in the first quarter of 2010.

### **Photocure wins patent case in USA**

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 is now remanded back to the USPTO to take appropriate steps on granting the requested patent term extension for Metvixia™. USPTO has an opening to appeal the judgement.

Photocure has a patent covering Metvixia™ in USA until March 2016 and based on the outcome of the patent case, this patent is now extended to July 27, 2018.

### **Financial position**

Sales revenues were NOK 29.1 million in the first quarter of 2009, compared to NOK 21.4 million in the first quarter of 2008, an increase of 36 %. The sales increase is due to NOK 2.3 million higher Hexvix sales and NOK 5.3 million higher Metvix/Aktelite sales. The higher Metvix/Aktelite sale was due to sale of more Aktelite lamps and more end user sale in the first quarter of 2009 as noted above.

Total revenue was NOK 29.1 million for the quarter, compared to NOK 22.7 million in same period last year. There was no milestone revenue in the first quarter of 2009. Milestone revenue for 2008 included the last accrual of NOK 1.3 million from Galderma related to signing of the agreement whereby Galderma became Photocure's commercial partner for Metvix/Aktelite outside the Nordic region.

Operating loss amounted to NOK 5.7 million, compared to NOK 22.5 million in the first quarter of 2008. Research and development expenses decreased by NOK 9.3 million compared to the first quarter of 2008. The marketing and sales expenses in the first quarter of 2009 is the same as the first quarter of 2008 reflecting the same level in commercial activities for Photocure.

General and administrative expenses were NOK 3.8 in the first quarter of 2009 compared to NOK 7.1 million in the first quarter of 2008. Photocure had general and administrative expenses of NOK 0.6 million and R&D expenses of NOK 3.5 million related to PCI Biotech Holding ASA/PCI Biotech AS in the first quarter of 2008.

Photocure owns 19.35 % in PCI Biotech Holding ASA, a cancer-focused drug delivery company that is developing a patented technology, known as photochemical internalization (PCI), to enhance the effect of anticancer drugs by targeted, light-directed drug delivery into cancer cells. Photocure's shares in PCI Biotech Holding were written down by NOK 4.2 million the first quarter of 2009, reflecting the market price NOK 7/share at the end of the first quarter 2009.

Net loss and comprehensive income for the first quarter of 2009 amounted to NOK 8.6 million compared to a net loss and comprehensive income of NOK 20.0 million in the first quarter of 2008.

Total equity for the Group totaled NOK 192.0 million at the end of March 2009 compared to NOK 199.7 million at the end of 2008. Liquid funds amounted to NOK 161.9 million at the end of March 2009, compared to NOK 179.9 million at the end of 2008. The number of outstanding shares was 22,093,301 at the end of March 2009.

29 April 2009

The Board of Directors of Photocure ASA

Photocure, the Photocure logo, Aktelite, Metvix and Hexvix are trademarks or registered trademarks of Photocure ASA.



The accounting policies adopted in this report are consistent with those followed in the preparation of the Group's annual financial statements for 2008 and complies with IFRS and IAS 34.

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

Q1 2009	Q1 2008		2009 1.1-31.3	2008 1.1-31.3	2008 1.1-31.12
29 073	21 411	Sales revenues	29 073	21 411	100 917
0	1 303	Signing fee and milestone revenues	0	1 303	1 303
<b>29 073</b>	<b>22 713</b>	<b>Total revenues</b>	<b>29 073</b>	<b>22 713</b>	<b>102 220</b>
-4 529	-4 501	Cost of products sold	-4 529	-4 501	-19 074
<b>24 545</b>	<b>18 212</b>	<b>Gross profit</b>	<b>24 545</b>	<b>18 212</b>	<b>83 147</b>
562	1 954	Other income	562	1 954	6 257
-2 668	-2 510	Indirect manufacturing expenses	-2 668	-2 510	-8 607
-11 688	-20 979	Research and development expenses	-11 688	-20 979	-84 303
-12 612	-12 009	Marketing and sales expenses	-12 612	-12 009	-45 916
-3 874	-7 140	General and administrative expenses	-3 874	-7 140	-17 951
<b>-5 734</b>	<b>-22 473</b>	<b>Operating profit/loss(-)</b>	<b>-5 734</b>	<b>-22 473</b>	<b>-67 374</b>
3 998	2 969	Financial income	3 998	2 969	16 103
-6 875	-520	Financial expenses	-6 875	-520	-13 111
<b>-2 877</b>	<b>2 449</b>	<b>Net financial profit/loss(-)</b>	<b>-2 877</b>	<b>2 449</b>	<b>2 991</b>
<b>-8 611</b>	<b>-20 024</b>	<b>Profit/loss(-) before tax</b>	<b>-8 611</b>	<b>-20 024</b>	<b>-64 382</b>
0	0	Tax expenses	0	0	0
<b>-8 611</b>	<b>-20 024</b>	<b>Net profit/loss(-)</b>	<b>-8 611</b>	<b>-20 024</b>	<b>-64 382</b>
0	0	Other comprehensive income	0	0	0
<b>-8 611</b>	<b>-20 024</b>	<b>Comprehensive income</b>	<b>-8 611</b>	<b>-20 024</b>	<b>-64 382</b>
-	-289	Incl. minority interests in the amount of	-	-289	-
-0,39	-0,91	Net income/loss(-) per share, undiluted (1)	-0,39	-0,91	-2,91
-0,39	-0,91	Net income/loss(-) per share, diluted (2)	-0,39	-0,91	-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)	1Q 2009				1Q 2008			
	Own	Partner	R&D*	Total	Own	Partner	R&D*	Total
Sales Metvix/Aktelite	8 081	11 323		19 404	5 640	8 450		14 090
Sales Hexvix	3 818	5 851		9 669	2 233	5 088		7 321
Sales revenue	11 899	17 174	0	29 073	7 872	13 538	0	21 411
Milestone revenue	0	0	0	0	0	1 303	0	1 303
<b>Total revenues</b>	<b>11 899</b>	<b>17 175</b>	<b>0</b>	<b>29 073</b>	<b>7 872</b>	<b>14 841</b>	<b>0</b>	<b>22 713</b>
Cost of goods sold	571	3 957	0	4 529	581	3 920	0	4 501
<b>Gross profit</b>	<b>11 328</b>	<b>13 217</b>	<b>0</b>	<b>24 545</b>	<b>7 292</b>	<b>10 921</b>	<b>0</b>	<b>18 212</b>
Gross profit %	95 %	77 %		84 %	93 %	74 %		80 %
Operating expenses	10 740	4 560	14 979	30 279	10 620	6 107	23 958	40 685
<b>Operating profit</b>	<b>587</b>	<b>8 657</b>	<b>-14 979</b>	<b>-5 734</b>	<b>-3 328</b>	<b>4 814</b>	<b>-23 958</b>	<b>-22 473</b>
Net finance	0	0	0	-2 877	0	0	0	2 449
<b>Profit before tax</b>	<b>587</b>	<b>8 657</b>	<b>-14 979</b>	<b>-8 611</b>	<b>-3 328</b>	<b>4 814</b>	<b>-23 958</b>	<b>-20 024</b>

\* Including share of general and administrative expenses



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

	31.03.2009	31.03.2008	31.12.2008
Intangible assets, software	511	760	534
Machinery & equipment	3 721	3 745	3 939
Other investments	7 336		11 528
<b>Total non-current assets</b>	<b>11 568</b>	<b>4 505</b>	<b>16 001</b>
Inventory	18 621	11 353	12 792
Receivables	29 924	25 296	29 158
Cash & cash equivalents	161 872	236 978	179 897
<b>Total current assets</b>	<b>210 418</b>	<b>273 627</b>	<b>221 846</b>
<b>Total assets</b>	<b>221 986</b>	<b>278 132</b>	<b>237 847</b>
Paid-in capital	11 047	11 047	11 047
Other paid-in capital	189 562	12 351	15 467
Retained earnings	-8 611	217 737	173 181
<b>Shareholders' equity</b>	<b>191 997</b>	<b>241 135</b>	<b>199 694</b>
Minority interest		202	
<b>Total equity</b>	<b>191 997</b>	<b>241 337</b>	<b>199 694</b>
Current liabilities	29 989	36 795	38 153
<b>Total liabilities</b>	<b>29 989</b>	<b>36 795</b>	<b>38 153</b>
<b>Total equity and liabilities</b>	<b>221 986</b>	<b>278 132</b>	<b>237 847</b>

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

Q1 2009	Q1 2008		2009 1.1-31.3	2008 1.1-31.3	2008 1.1-31.12
199 694	259 994	<b>Equity at beginning of period</b>	199 694	259 994	259 994
0	0	Share issue, employees	0	0	
0	0	Share issue	0	0	
914	1 366	Share-based compensation	914	1 366	4 483
0	0	De-merger of PCI Biotech/ Investment	0	0	-400
0	0	Net gain de-consolidation PCI Biotech	0	0	0
-8 611	-20 024	Net income/loss(-) for the period	-8 611	-20 024	-64 382
<b>191 997</b>	<b>241 336</b>	<b>Equity at end of period</b>	<b>191 997</b>	<b>241 337</b>	<b>199 694</b>

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

Q1 2009	Q1 2008		2009 1.1-31.3	2008 1.1-31.3	2008 1.1-31.12
-8 611	-20 024	Income/loss(-) before tax	-8 611	-20 024	-64 382
-11 766	1 757	Other operational items	-11 766	1 757	4 704
<b>-20 378</b>	<b>-18 267</b>	<b>Net cash flow from operations</b>	<b>-20 378</b>	<b>-18 267</b>	<b>-59 679</b>
2 353	2 794	Cash flow from investments	2 353	2 794	-12 865
0	-3	Cash flow from capital transactions	0	-3	-13
<b>-18 025</b>	<b>-15 475</b>	<b>Net change in cash during the period</b>	<b>-18 025</b>	<b>-15 475</b>	<b>-72 556</b>
179 897	252 452	Cash & cash equivalents at beginning of period	179 897	252 452	252 452
<b>161 872</b>	<b>236 977</b>	<b>Cash &amp; cash equivalents at end of period</b>	<b>161 872</b>	<b>236 977</b>	<b>179 896</b>