



# **Highlights for first quarter 2017**

(Numbers in brackets and comparisons are for the corresponding period in 2016.

- Total Hexvix/Cysview global in-market sales increased 7% to NOK 65 million (NOK 61 million) in the first quarter
- Total revenue increased 5% to NOK 36.5 million (NOK 34.9 million) in the first quarter. Hexvix/Cysview revenue increased 9%, and 14% in constant currencies
- In-market unit sales increased 10% driven by growth of 28% in the US, 13% for partner sales and a decline of 8% in Nordic
- Commercial segment EBITDA was NOK 4.9 million (NOK 5.3 million) for the first quarter with EBITDA margin of 14%
- In May, results from the Phase 3 study with Blue Light Flexible Cystoscopy (BLFC™) with Hexvix®/Cysview®\* were presented at AUA meeting - Cysview provided a highly significant (p<0.0001) improvement of 21.5 % in detecting patients with bladder cancer in the surveillance setting compared to white light alone
- In April, a strategic update was announced stating that, following non-conclusive partnering discussions, the company will assess further strategic alternatives for Cevira and Visonac

#### Key figures:

Figures in NOK million	Q1 2017	Q1 2016	Change	FY 2016
Hexvix/Cysview revenues	36.5	33.5	9 %	131.0
Other sales & milestone revenues	-	1.3		12.7
Total revenues	36.5	34.9	5 %	143.6
Operating expenses	37.9	36.2	5 %	142.3
EBITDA recurring	-4.2	-3.7		-8.0
EBITDA commercial franchise	4.9	5.3		30.0
EBITDA development portfolio	-9.2	-9.1		-38.1
EBIT (Operating result)	-10.4	-4.9		-15.9
Profit/loss(-) before tax	-9.3	-4.4		12.8
Net Profit/loss(-)	-6.9	-0.7		35.3
Earnings per share, diluted (NOK)	-0.32	-0.03		1.64
Cash & cash equivalents	155.5	120.6		169.2

#### President & CEO Kjetil Hestdal, M.D. Ph.D. comments:

"Hexvix/Cysview delivered strong growth in major markets, outside the Nordic regions, during the first quarter. In particular, we saw good momentum in the US, driven by strong demand for Cysview. As planned, we increased our investment in sales and marketing in the US during the quarter in order to drive further awareness in Cysview and growth in the region. This investment will continue through 2017 and 2018. After the quarter end, we were very pleased to report positive data from our Phase 3 study in the bladder cancer surveillance setting. Obtaining these convincing results of the study was a significant milestone and foundation for our future expansion strategy in the US. The surveillance market is an attractive market for Photocure and is an important component of our long-term growth plans in the US. We are preparing to file the data from the Phase 3 study with the FDA later this year to support a potential expansion in this setting."



# **Operational review**

Photocure's strategy is to create a specialty pharmaceutical company maximizing its commercial presence and the opportunity of its flagship brand Hexvix®/Cysview® in urology. In addition, the Company will continue to leverage its competence in its proprietary Photodynamic Technology Platform and expertise and capacity in urology to explore, alone or in partnership with others, new product opportunities targeting unmet medical needs in urology.

The company is also assessing strategic alternatives for its non-urology assets, Cevira® and Visonac®, which target therapeutic areas with significant unmet medical needs.

#### **Update commercial segment**

The commercial segment continued to show improved sales in the quarter. First quarter total revenue increased 5% to NOK 36.5 million (NOK 34.9 million) compared to last year, driven by improvements in sales performance for Hexvix/Cysview, particularly in US, partly offset by negative impact from currency translation as well as no sales of API and no milestone revenues in the quarter.

Operating expenses increased 6% to NOK 28.7 million (NOK 27.2 million) in the first quarter. This was driven by planned increased marketing efforts in US.

EBITDA for the first quarter was NOK 4.9 million (NOK 5.3 million) The decline from last year was expected. First quarter EBITDA margin was 14%, compared to 15% first quarter last year.

MNOK	YTD '17	YTD '16	FY '16
Nordic - Hexvix US - Cysview Partners Hexvix/Cysview total YoY growth Signing fee & milest. Total revenues YoY growth	9.7 10.0 16.7 <b>36.5</b> <i>9</i> % 0.0 <b>36.5</b> <i>5</i> %	10.1 7.6 15.8 <b>33.5</b> 1.3 <b>34.9</b>	39.0 30.5 61.5 <b>131.0</b> 7.4 <b>143.6</b>
Cost of goods sold Gross profit Operating expenses EBITDA	-2.9 <b>33.7</b> -28.7 <b>4.9</b>	-2.4 <b>32.5</b> -27.2 <b>5.3</b>	-9.3 <b>134.3</b> -104.2 <b>30.0</b>
EBITDA margin	14 %	15 %	21 %

#### Hexvix®/Cysview® – profitable growth

Global in-market sales of Hexvix/Cysview increased 7% to NOK 65 million (NOK 61 million) in the first quarter. Global in-market unit sales increased 10% in the first quarter compared to 2016. Sales development in US was strong, but consolidated volume growth was impacted by slowing growth and declines in more mature markets, especially in the Nordic region.

Total sales revenues for Hexvix/Cysview increased 9% to NOK 36.5 million (NOK 33.5 million) in the first quarter, driven by increased demand in US and price increases more than offsetting negative impact from foreign currency translation. Revenue growth in constant currencies was 14% for the quarter.

#### Nordic Hexvix sales

Nordic revenues decreased 4% to NOK 9.7 million (NOK 10.1 million) in the first quarter driven by lower demand and negative impact from foreign currency translation, partly offset by price increases. Revenue in constant currencies grew 1% in the quarter.

Photocure's in-market unit sales in the Nordic region in first quarter was 8% less compared to same quarter last year. We had weak results across the region, with Denmark as the main driver due to temporary issues related to reorganization of hospitals in the Copenhagen region.

#### US Cysview sales

First quarter revenue in the US increased 32% to NOK 10.0 million (NOK 7.6 million) compared to the prior year, driven by volume growth and price increases, but negatively impacted by a 2% decline in average quarter currency rate. In constant currency, first quarter revenue grew 36% compared to last year. Unit sales in the US increased 28% in the first quarter.

US growth was driven both by the number of permanent blue light cystoscopes (BLCs) installed at leading US hospitals/urology centers and by increased average usage per center. The total number of permanent BLCs installed at leading US hospitals/urology centers at the end of first quarter was 89, an increase of 6 units compared to the number of BLCs installed at the end of 2016.

Photocure is in the process of expanding its salesforce in US to increase penetration of Cysview in hospitals and urology practices.

In the US we have established a real-world registry study at nine sites across the US. In 2016, the registry reached more than 600 patients, of which



more than 360 patients were enrolled during 2016. The registry study has already resulted in numerous podium and abstract presentations at national and international scientific urological meetings, including the American Urological Association (AUA) Annual Meeting May 2017. The plan is that this will continue to allow for publications of additional clinical data supporting the medical benefits of Hexvix/Cysview.

Photocure continues to work to secure a long-term sustainable solution for Cysview Medicare reimbursement. The bill introduced in the last Congressional session was not voted on in 2016. Based on the continued support, a similar bill is under preparation for introduction in the current Congress. We expect the new bill to gain bi-partisan support of a cross section of Congressional members, however, the timing of a final resolution is uncertain.

#### Hexvix/Cysview partner sales

Partner revenue increased 6% to NOK 16.7 million (NOK 15.8 million) in the first quarter, negatively impacted by currency translation and delays in new markets. Revenue in constant currency grew 12% for the quarter.

End user unit sales increased 13% in the first quarter. Sales in the new markets, Canada and Australia, have commenced, however volume has been negatively impacted by timing of outplacement of scopes by the third-party suppliers and timing of health system funding approvals.

In November 2016, new French National Guidelines for the management of Bladder Cancer were introduced. The French guidelines recommend BLC with Hexvix for the first bladder cancer resection (TURBT) in essentially all patients and for consecutive TURBT's in the majority of patients. Hexvix has however been removed from the "Listeen-sus" in France and has lost reimbursement from second quarter 2017. We do not expect this to have material financial impact.

#### **Update development portfolio**

# Hexvix®/Cysview® – expansion opportunities

Hexvix/Cysview is currently used to optimize patient management through improved diagnosis and bladder cancer resection (TURB) in a surgical procedure using rigid cystoscopes. After patients are initially diagnosed and treated by TURB, they undergo cystoscopy examinations every 3-9 months. This surveillance is performed in the outpatient/office setting using flexible cystoscopes to detect any suspicious new lesions requiring referral for additional TURBs. An expansion of the use of Hexvix/Cysview into the surveillance patient segment

will open a market segment estimated to have a total market size of 2-3 times the current segment.

A phase 3 clinical study examining bladder cancer detection rates using Blue Light Flexible Cystoscopy with Cysview vs white light flexible cystoscopy began in the fourth quarter of 2015. Final results from this study were presented at the AUA meeting in Boston, May 2017.

The results, presented during a late-breaking plenary abstract session, showed that the study met its primary endpoint. Blue Light Flexible Cystoscopy (BLFC) with Cysview showed a highly significant (p<0.0001) improvement in detecting additional patients (21.5%) with bladder cancer in the surveillance setting. Furthermore, Blue Light Cystoscopy with Cysview in the follow-up TURB examination increased the detection of malignancies compared to White Light Cystoscopy (WLC), showing a highly significant (p<0.0001) improvement of detection of patients with flat high grade bladder cancer lesions (CIS) of 34.6%. In addition, the repeated use of Cysview did not increase adverse event frequency.

Based on these positive results, we will continue the preparation of the filing of a supplemental NDA later this year, with a possible FDA approval and a commercial launch in the out-patient surveillance market in 2018.

# Visonac® and Cevira® – late stage clinical non-urology development products

In April, the company announced that it will assess further strategic alternatives for its non-urology assets, Cevira and Visonac, in parallel with ongoing partner search.

The decision to initiate a broad review of possible strategic alternatives for Cevira and Visonac follows a non-conclusive comprehensive partnering process. Photocure has experienced substantial interest with several possible partners having recognized the unmet medical need in the target therapeutic areas, and has engaged in thorough discussions and due diligence for both Cevira and Visonac. However, at this stage remaining development risk is expressed as a concern for establishing an optimal partnership for Cevira, while the current combination of drug and device is an expressed commercial concern for Visonac.

Based on the input received in the partnering process, Photocure has decided to broaden its review of strategic alternatives for Cevira and Visonac.



## Other business updates

In April, Photocure and Bellus Medical, a privately owned US based cosmetic dermatology company, signed an asset purchase and licensing agreement for Photocure's cosmetic dermatology product Allumera. In this agreement Photocure will receive certain milestones as well as royalties on sales of Allumera from Bellus Medical.

## **Financial review**

(Numbers in brackets are for the corresponding period in 2016; references to the prior year refer to a comparison to the same period 2016, unless otherwise stated).

First quarter results were driven by strong performance in US offset by impact from foreign currency translation as well as increased operational costs.

#### Revenues

Total revenues in the first quarter were NOK 36.5 million, an increase of 5% from the first quarter last year (NOK 34.9 million).

Hexvix/Cysview sales revenues for the first quarter were NOK 36.5 million, an increase of 9% from last year (NOK 33.5 million). First quarter revenues were negatively impacted by foreign exchange as revenue increase in constant currencies was 14%. The increase was driven by continued market penetration of Hexvix/Cysview, particularly in US, as well as price increases.

#### Operating costs

Total operating costs, excluding one-off items, depreciation and amortization, were NOK 37.9 million (NOK 36.2 million) in the first quarter, an increase of 5%.

MNOK	YTD '17	YTD '16	FY '16
Research & Development YoY growth	4.5 -10 %	5.0	17.7
Sales & Marketing  YoY growth	22.0 9 %	20.1	79.3
Other Opex  YoY growth	11.5 3%	11.1	45.3
Operating expenses excl one-off	37.9	36.2	142.3
YoY growth	5 %		
Nedax write-down	4.0	0.0	0.0
Operating expenses	41.9	36.2	142.3
Depreciation & Amort.	2.2	1.1	7.9
Total	44.1	37.3	150.2

The increase in first quarter operating costs was driven by planned investments in US sales and marketing operations, partly offset by a decline in R&D spending and impact from currency translation.

First quarter R&D costs were NOK 4.5 million (NOK 5.0 million). The decrease reflects a reduction in expenses for Visonac and Cevira. The R&D costs relate mainly to regulatory work and maintenance and expansion of our intellectual property as well as the development of the current pipeline. Expenses related to the Cysview Phase 3 market expansion trial are capitalized and amortized.

Marketing and sales costs increased 9% to NOK 22.0 million (NOK 20.1 million) in the first quarter. The increase was in line with our strategic plans and was driven by activities in US. As announced in the fourth quarter 2016 report Photocure will increase spending in US operations in 2017 and 2018.

Other operating expenses, which includes supply chain, business development and general/administration, was at level with first quarter last year.

One-off items relate to write off of parts and finished goods inventory for Nedax. As announced in April 2017, following non-conclusive partnering discussions for Cevira and Visonac, Photocure will assess other strategic alternatives for these two opportunities in parallel to ongoing partner search.

The company has no additional significant capitalized assets at quarter end for Cevira and Visonac.

#### Financial results

EBITDA, before one-off items, was negative NOK 4.2 million (NOK -3.7 million) for the first quarter. Including one-off items EBITDA was NOK -8.2 million (NOK -3.7 million). Currency translation had a negative effect on the results of approximately NOK 1 million for the first quarter.

EBITDA in the commercial segment was NOK 4.9 million for the first quarter compared to NOK 5.3 million prior year. The development portfolio had EBITDA after one-off items of NOK -13.2 million for the first quarter compared to NOK -9.1 million prior year.

First quarter depreciation and amortization was NOK 2.2 million (NOK 1.1 million). The increase from prior year was mainly driven by amortization on the investments in intangible assets related to the Phase 3 market expansion trial for Cysview.

Net financial items were NOK 1.1 million (NOK 0.5 million) for the first quarter.



Photocure had a net loss before tax of NOK 9.3 million in the first quarter (net loss of NOK 4.4 million). Tax expenses in the first quarter were a net income of NOK 2.4 million (net income NOK 3.6 million). The net tax income was driven by losses in the quarter. Net result was NOK 6.9 million (loss of NOK 0.7 million) in the first quarter.

#### Cash flow and statement of financial position

Net cash flow from operations was negative NOK 10.8 million in the first quarter (negative NOK 9.3 million). The impact from changes to working capital was negative NOK 3.7 million (negative NOK 5.2 million)

Net cash flow from investments was negative NOK 3.0 million in the first quarter (negative NOK 5.1 million). This includes investments in intangible assets of NOK 4.0 million (NOK 4.1 million), mainly related to the Phase 3 market expansion trial for Cysview.

Cash and cash equivalents were NOK 155.5 million at the end of the first quarter. First quarter net change in cash was negative NOK 13.8 million (negative NOK 13.4 million).

Shareholders' equity was NOK 245.9 million at end of first quarter, an equity ratio of 88%. At the end of 2016, shareholders' equity was NOK 251.9 million (equity ratio of 86%).

As of 31 March 2017, Photocure held 809 own shares.

# Risks and uncertainty factors

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

The most important risks the company is exposed to are associated with market development for Hexvix/Cysview, progress of partnering activities, as

well as financial risks related to interest rates, liquidity and currency fluctuations.

There are no significant changes in the risks and uncertainty factors compared to the descriptions in the Annual Report for 2016.

#### Outlook

Photocure has built considerable experience in the urology sector through its Hexvix/Cysview franchise and sees significant long-term value creation potential in this market segment. The company has over the last years experienced a strong and growing penetration of Hexvix in key European markets and aims to capitalize on the inclusion in the AUA guidelines, as well as the increased patient awareness, to significantly increase penetration in the US market.

Photocure believes that in order to increase market shares in the US to European levels an investment in the US salesforce is required. As stated previously, the company plans to double its salesforce from 2016 and increase sales and marketing expenses towards the end of 2017. The goal of these efforts is to quadruple the revenues from the US operations to a range of USD 15 million by 2020. As a result of the increased activity level, the added operating expenses will contribute to an EBITDA decline for the group in 2017 and 2018. The company is fully funded for this market strategy.

Photocure will continue to work on reimbursement in the US and will utilize the increased body of evidence from recent publications documenting the medical benefits of Blue Light Cystoscopy with Hexvix/Cysview to demonstrate its clinical benefits.

Photocure reported in May this year that the Phase 3 study of Hexvix/Cysview in the surveillance patient segment met its primary endpoint and other major endpoints. Based on this the company plans to submit an sNDA to the US FDA, with a possible approval in 2018, for use of Blue Light Flexible Cystoscopy with Cysview in this out-patient surveillance setting.



# The Board of Directors and CEO Photocure ASA

Oslo, 22 May 2017

Jan Hendrik Egberts<br/>ChairpersonJohanna Holldack<br/>DirectorGwen Melincoff<br/>DirectorTom Pike<br/>DirectorSynne H. Røine<br/>DirectorGrannum R. Sant<br/>DirectorXavier Yon<br/>DirectorKjetil Hestdal<br/>President and CEO



# **Photocure Group Accounts for first quarter 2017**

# Photocure Group – Statement of comprehensive income

		2017	2016	2016
(all amounts in NOK 1 000 except per share data)	Note	Q1	Q1	1.1-31.12
Sales revenues		36,514	33,531	136,186
Signing fees and milestone revenues		-	1,321	7,441
Total revenues		36,514	34,852	143,627
Cost of goods sold		-2,853	-2,371	-9,337
Gross profit		33,661	32,481	134,291
Indirect manufacturing expenses	3	-2,681	-2,752	-10,386
Research and development expenses	3	-10,022	-5,615	-22,962
Marketing and sales expenses	3	-21,995	-20,146	-79,930
Other operating expenses	3	-9,353	-8,836	-36,874
Total operating expenses		-44,051	-37,349	-150,152
EBIT		-10,390	-4,868	-15,861
Financial income		1,632	1,282	32,427
Financial expenses		-547	-768	-3,787
Net financial profit/loss(-)		1,085	515	28,640
Profit/loss(-) before tax		-9,305	-4,353	12,779
Tax expenses	4	2,378	3,647	22,530
Net profit/loss(-)		-6,927	-706	35,309
Other comprehensive income	5	-313	2,373	-366
Total comprehensive income		-7,240	1,667	34,943
Net profit/loss(-) per share, undiluted	6	-0.32	-0.03	1.64
Net profit/loss(-) per share, diluted	6	-0.32	-0.03	1.64



# **Photocure Group – Statement of financial position**

(Amounto in NOK 1 000)	Note	31.03.2017	31.03.2016	31.12.2016
(Amounts in NOK 1 000)  Non-currrent assets	Note	31.03.2017	31.03.2010	31.12.2010
Machinery & equipment	7	1,484	1,980	1,660
Intangible assets	7	28,382	16,926	26,390
Other investments	,	20,002	8,574	20,000
Deferred tax asset	4	48,398	27,137	46,020
Total non-current assets	7	<b>78,264</b>	54,617	<b>74,070</b>
Total Holl Galletti assets		70,204	04,017	74,070
Current assets				
Inventories		14,436	17,620	17,955
Accounts receivable		14,660	9,866	12,323
Other receivables		15,304	46,759	12,750
Cash and short term deposits	8	155,466	120,622	169,239
Total current assets		199,865	194,867	212,268
Total assets		278,129	249,484	286,338
Equity and liabilities				
Equity				
Share capital	9	10,779	10,738	10,779
Other paid-in capital		55,594	49,805	54,268
Retained earnings		179,535	152,968	186,895
Shareholders' equity		245,908	213,511	251,943
Long-term liabilities				
Pension liabilities		3,955	4,216	3,758
Total long-term liabilities		3,955	4,216	3,758
Current liabilities		28,267	31,757	30,637
Total liabilities		32,222	35,973	34,395
Total equity and liabilities		278,129	249,484	286,338

# **Photocure Group – Changes in equity**

(Amounts in NOK 1 000)	2017 Q1	2016 Q1	2016 1.1-31.12
Equity at beginning of period	251,943	210,060	210,060
Capital increase	425		2,415
Share-based compensation (share options employees)	781	800	3,300
Treasury shares decrease		984	1,225
Comprehensive income	-7,240	1,667	34,943
Equity at end of period	245,908	213,511	251,943



# **Photocure Group – Cash flow statement**

	2017	2016	2016
(Amounts in NOK 1 000)	Q1	Q1	1.1-31.12
Profit/loss(-) before tax	-9,305	-4,353	12,779
Depreciation and amortisation	2,151	1,148	7,853
Gain sale of financial asets	-	-	-27,280
Share-based compensation	941	800	3,541
Net interest income	-1,008	-771	-2,394
Settlement deferred revenue Galderma	-	-	37,193
Changes in working capital	-3,742	-5,219	-8,787
Other operational items	151	-867	-3,713
Net cash flow from operations	-10,812	-9,263	19,193
Net investments in fixed assets	-17	-1,759	-3,148
Development expenditures	-3,952	-4,137	-18,567
Sales proceeds shares PCI Biotech Holding	-	-	33,213
Received interest payments	1,008	771	2,394
Cash flow from investments	-2,961	-5,126	13,892
Cash flow from financing activities	-	984	2,128
Net change in cash during the period	-13,773	-13,404	35,213
Cash & cash equivalents at beginning of period	169,239	134,026	134,026
Cash & cash equivalents at end of period	155,466	120,622	169,239



# Notes to the accounts for first quarter 2017

## Note 1 – General accounting principles

#### **General information**

Photocure ASA is a public limited company domiciled in Norway. The business of the Company is associated with research, development, production, distribution, marketing and sales of pharmaceutical products and related technical medical equipment. The Company's shares are listed on the Oslo Stock Exchange (OSE: PHO). The Company's registered office is Hoffsveien 4, NO-0275 Oslo, Norway.

Photocure Group (Photocure) comprises Photocure ASA and the wholly owned subsidiary Photocure Inc. that is a US registered company.

#### **Basis of preparation**

These condensed interim financial statements have been prepared in accordance with IAS 34 Interim Financial Reporting. These interim financial statements should be read in conjunction with the consolidated financial statements for the year ended 31 December 2016 (the Annual Financial Statements) as they provide an update of previously reported information. The accounting policies used are consistent with those used in the Annual Financial Statements. The presentation of the interim financial statements is consistent with the Annual Financial Statements. The interim report has not been subject to an audit. The Board of Directors approved the interim financial statements on 22 May 2017.

Photocure has Norwegian kroner (NOK) as its functional currency and presentation currency. In the absence of any statement to the contrary, all financial information is reported in whole thousands. As a result of rounding adjustments, the figures in the financial statements may not add up to the totals.

#### Summary of significant accounting policies

IFRS 15 Revenue from contract with customers establishes a comprehensive framework for determining whether, how much and when revenue is recognized. The standard replaces IAS 18 Revenue and related interpretations. IFRS 15 is effective for annual reporting periods beginning on or after 1 January 2018. The new standard contains a new set of principles on when and how to recognize and measure revenue as well as new requirements related to presentation. The core principle in that framework is that revenue should be recognized dependent on the transfer of promised goods or services to the customer for an amount that reflects the consideration which should be received in exchange for those goods or services. The objective of the standard is to provide a five-step approach to revenue recognition that includes identifying contracts with customers, identifying performance obligations, determining transaction prices, allocating transaction prices to performance obligations, and recognizing revenue when or as performance obligations are satisfied.

The Group is continuing to assess the potential impact of IFRS 15. The adoption of IFRS 15 is not expected to have a significant impact on Photocure's recognition of sale of goods, but might affect the timing of the recognition of upfront payment and milestone fees.

Photocure is analyzing the impact of implementing IFRS 9 Financial Instruments and IFRS 16 Leases from 1.1.2019. Based on the financial assets and liabilities currently held by the company these are not expected to have a significant impact on Photocure's financial statements.

The new and amended standards and interpretations from IFRS that were adopted by the EU with effect from 2017 did not have any significant impact on the reporting in 2017.

#### Important accounting valuations, estimates and assumptions

Preparation of the accounts in accordance with IFRS requires the use of judgment, estimates and assumptions that have consequences for recognition in the balance sheet of assets and liabilities, the estimation of contingent



liabilities and recorded revenues and expenses. The use of estimates and assumptions is based on the best discretionary judgment of the Group management.

## Note 2 - Photocure Group - Segment information

Photocure has two segments; Commercial Franchise and Development Portfolio. Commercial Franchise includes Hexvix/Cysview by sales channel, own sales and partner sales, and other sales, currently including sale of active ingredients. Development Portfolio includes development of commercial products and pipeline products.

1 Jan - 31 March 2017		Commercial Franchise			Development Portfolio				
(Amounts in NOK 1 000)	Hex/Cys	Hex/Cys	Other	Total	Hex/Cys		Total	Grand	
	Own Sales	Partner	Sales	Sales	Develop.	Pipeline	R&D	Total	
Sales revenues	19,772	16,742	-	36,514	=	-	-	36,514	
Milestone revenues	-	-	-	-	-	-	-	-	
Cost of goods sold	-768	-2,085	-	-2,853	-	-	-	-2,853	
Gross profit	19,004	14,657	-	33,661	-	-	-	33,661	
Gross profit of sales %	96 %	88 %		92 %				92 %	
R&D	-	-	-	-	-825	-7,625	-8,450	-8,450	
Sales & marketing	-19,071	-1,885	-	-20,956	-	-1,020	-1,020	-21,977	
Other & allocations	-3,093	-4,480	-188	-7,761	-966	-2,747	-3,713	-11,474	
Operating expenses	-22,164	-6,365	-188	-28,717	-1,791	-11,392	-13,183	-41,900	
EBITDA	-3,160	8,292	-188	4,944	-1,791	-11,392	-13,183	-8,239	

1 Jan - 31 March 2016	Commercial Franchise Development Portfolio				rtfolio			
(Amounts in NOK 1 000)	Hex/Cys	Hex/Cys	Other	Total	Hex/Cys		Total	Grand
	Own Sales	Partner	Sales	Sales	Develop.	Pipeline	R&D	Total
Sales revenues	17,725	15,806	-	33,531	-	-	-	33,531
Milestone revenues	-	-	1,320	1,320	-	-	-	1,320
Cost of goods sold	-648	-1,722	-	-2,371	-	-	-	-2,371
Gross profit	17,077	14,084	1,320	32,481	-	-	-	32,481
Gross profit of sales %	96 %	89 %		93 %				93 %
R&D	-	-	-	-	-822	-4,148	-4,970	-4,970
Sales & marketing	-17,365	-1,889	-	-19,254	-	-828	-828	-20,082
Other & allocations	-3,013	-4,726	-159	-7,897	-827	-2,426	-3,253	-11,150
Operating expenses	-20,378	-6,615	-159	-27,151	-1,649	-7,402	-9,050	-36,202
EBITDA	-3,301	7,469	1,162	5,330	-1,649	-7,402	-9,050	-3,721

1 Jan - 31 December 2016		Commercial Products			Development Products				
(Amounts in NOK 1 000)	Hex/Cys	Hex/Cys	Other	Total	Hex/Cys		Total	Grand	
	Own Sales	Partner	Sales	Sales	Develop.	Pipeline	R&D	Total	
Sales revenues	69,504	61,460	5,222	136,186	-	-	-	136,186	
Milestone revenues	-	2,311	5,130	7,441	-	-	-	7,441	
Cost of goods sold	-2,701	-6,635	-	-9,337	-	-	-	-9,337	
Gross profit	66,803	57,136	10,352	134,291	-	-	-	134,291	
Gross profit of sales %	96 %	89 %	100 %	93 %				93 %	
R&D	-	-	-	-	-4,215	-13,437	-17,652	-17,652	
Sales & marketing	-68,230	-7,541	-	-75,771	-	-3,555	-3,555	-79,326	
Other & allocations	-11,037	-16,802	-632	-28,472	-3,187	-13,661	-16,848	-45,320	
Operating expenses	-79,268	-24,343	-632	-104,243	-7,401	-30,654	-38,055	-142,298	
EBITDA	-12,465	32,793	9,719	30,047	-7,401	-30,654	-38,055	-8,008	



## Note 3 – Income statement classified by nature

	2017	2016	2016
(Amounts in NOK 1 000)	Q1	Q1	1.1-31.12
Sales revenues	36,514	33,531	136,186
Signing fees and milestone revenues	-	1,321	7,441
Cost of goods sold	-2,853	-2,371	-9,337
Gross profit	33,661	32,481	134,291
Payroll expenses	-22,656	-22,100	-82,385
R&D costs excl. payroll expenses/other operating exp	-5,724	-2,229	-7,542
Ordinary depreciation and amortisation	-2,151	-1,148	-7,853
Other operating expenses	-13,520	-11,872	-52,373
Total operating expenses	-44,051	-37,349	-150,152
EBIT	-10,390	-4,868	-15,861

#### Note 4 – Tax

(Amounts in NOK 1 000)	31.03.2017	31.12.2016
Income tax expense		
Tax payable	-	-
Changes in deferred tax	-2,378	-22,530
Total income tax expense	-2,378	-22,530
Tax base calculation		
Profit before income tax	-7,149	18,685
Permanent differences	-695	-27,426
Temporary differences	858	19,044
Utilisation of tax loss carried forward	-	-10,303
Change in tax loss carried forward	1,215	-
Tax base	-5,771	0
Temporary differences:		
Total	-113,680	-122,268
Tax loss carried forward	315,339	314,019
Net temporary differences	201,659	191,751
Unrecognised deductible temporary differences and tax losses		
Deferred tax benefit	201,659	191,751
Deferred tax asset	48,398	46,020

Temporary differences are recognized for the parent company only and the note disclosure for the Group is of this reason identical to the disclosure for parent company.

The parent company has recognized a deferred tax asset regarding net temporary differences. Accumulated tax asset in the parent company at the end of March 2017 is NOK 48.4 million compared to NOK 46.0 million at end of 2016. There is no expiry on losses to be carried forward in Norway. The basis for recognition of a tax asset in Norway is the estimated future profit according to the business plan for all major markets and that temporary differences for the coming years will be reversed. The deferred tax asset has increased by NOK 2.4 million as of 31 March 2017. The basis for the recognition of the tax asset is the assessment that there is convincing evidence that the deferred tax benefit will be utilized.



# Note 5 – Other comprehensive income

	2017	2016	2016
(Amounts in NOK 1 000)	Q1	Q1	1.1-31.12
Market value adjustment PCI Biotech Holding ASA		2,640	-
Currency translation	-313	-267	865
Total other comprehensive income	-313	2,373	865

Items may be subsequently reclassified to profit or loss.

#### Note 6 – Earnings per share

Earnings per share is calculated on the basis of the profit/loss for the year after tax but excluding other comprehensive income. The result is divided by the weighted average number of outstanding shares over the year, reduced by acquired treasury shares. The diluted earnings per share is calculated by adjusting the average number of outstanding shares with the number of employee options that can be exercised. Antidilution effects are not taken into consideration.

	2017	2016
(Figures indicate the number of shares)	1.1-31.03	1.1-31.12
Issued ordinary shares 1 January	21,557,910	21,476,295
Effect of treasury shares Effect of share options exercised	-809 -	-809 -54,730
Effect of shares issued Weighted average number of shares	21,557,101	81,615 <b>21,502,371</b>
Effect of outstanding share options	83,730	128,971
Weighted average number of diluted shares	21,640,831	21,631,342
Earnings per share in NOK	-0.32	1.64
Earnings per share in NOK diluted	-0.32	1.64

#### Note 7 - Fixed Assets

(Amounts in NOK 1 000)	Machinery & equipment	Intangible
Net book value 31.12.16	1,660	26,390
Net investments 31.03.17	17	3,952
Depreciation and amortization	-193	-1,960
Net book value 31.03.17	1,484	28,382

Photocure has from 2015 capitalized a new clinical study for Cysview in US and a project for new solvent device.



#### Note 8 - Fair value

The table below analyses financial assets recognized in the balance sheet at fair value according to the valuation method.

The different levels have been defined as follows:

Level 1: Noted prices in active markets for corresponding assets or liabilities

Level 2: Available value measurements other than the noted prices classified as Level 1, either

directly observable in the form of agreed prices or indirectly as derived from the

price of equivalent.

Level 3: Value measurements of assets or liabilities that are not based on observed market values

Market value hierarchy				
(Amounts in NOK 1 000)	Level 1	Level 2	Level 3	Total
Financial assets available for sale:				
- Money market funds	130,671	-	-	130,671
Total	130,671	-	-	130,671

## Note 9 – Share capital

Registered share capital in Photocure ASA amounts to:

	No. of shares	Nominal value per share	Share capital in NOK
Share capital at 31 December 2016	21,557,910	NOK 0.50	10,778,955
Share capital at 31 March 2017	21,557,910	NOK 0.50	10,778,955
Treasury shares:			
Holdings of treasury shares at 31 December 2016	809		405
Buy-back of treasury shares	-	NOK 0.50	-
Share option exercise	-	NOK 0.50	-
Holdings of treasury shares at 31 March 2017	809		405

The table below indicates the status of authorizations at 31 March 2016:

(Figures indicate the number of shares)	Purchase, treasury shares	Ordinary share issue	Employee share issues
Authorisation issued at the General Meeting on 28 April 2016	2,147,628	2,147,628	2,147,628
Share issues after the General Meeting on 28 April 2016	-	-	81,615
Purchase of treasury shares	-	-	-
Remaining under authorisations at 31 March 2017	2,147,628	2,147,628	2,066,013



Shares owned, directly or indirectly, by members of the board, the President and CEO and senior management and their closely related associates as of 31 March 2017:

Name	Position	No. of shares	No. of subscription rights
Kjetil Hestdal	President and CEO	128,873	93,500
Ambaw Bellete	Head, US Cancer Commercial Operations	-	76,600
Erik Dahl	Chief Financial Officer	1,000	93,500
Inger Ferner Heglund	Vice President Research and Development	8,200	90,580
Grete Hogstad	Vice President Strategic Marketing	10,500	77,800
Espen Njåstein	Head, Nordic Cancer Commercial Operatio	5,000	80,450
Gry Stensrud	Vice President Technical Development & C	1,845	73,850
Tom Pike	Board member	3,400	-

## Note 10 – Share options

At 31 March 2017, employees in Photocure had the following share option schemes:

Year of allocation				
	2016	2015	2014	2012
Option programme	2016	2015	2014	2012
Number	327,200	294,970	100,001	227,117
Exercise price (NOK)	40.15	32.78	27.39	38.50
Date of expiry (31 December)	2020	2019	2018	2017

The number of employee options and average exercise prices for Photocure, and developments during the year:

	31.03.	2017	31.12	.2016
	No. of shares			Average exercise price (NOK)
Outstanding at start of year	951,955	36.10	1,119,543	37.00
Allocated during the year	-	-	354,100	40.15
Became invalid during the year	-	-	234,987	40.75
Exercised during the year	2,667	27.39	116,282	29.22
Expired during the year	-	-	170,419	48.75
Outstanding at end of period	949,288	36.12	951,955	36.10
Exercisable options at end of period	818,735	36.36	620,772	35.28

Average exercise price for allocated, invalid, outstanding and exercisable options are all adjusted for paid dividend of NOK 2.00 in 2013.



# Note 11 - Shareholders

Overview of the major shareholders at 31 March 2017:

	Account			
Shareholder	type	Citizen	No of shares	%
HIGH SEAS AS		NOR	4,000,000	18.55 %
J.P. MORGAN CHASE BANK N.A. LONDON	NOM	GBR	3,164,686	14.68 %
KLP AKSJE NORGE VPF		NOR	1,218,130	5.65 %
RADIUMHOSPITALETS FORSKNINGSSTIFTELSE		NOR	1,022,916	4.74 %
FONDSFINANS NORGE		NOR	915,000	4.24 %
KOMMUNAL LANDSPENSJONSKASSE		NOR	838,272	3.89 %
MP PENSJON PK		NOR	610,000	2.83 %
DANSKE INVEST NORSKE INSTIT. II.		NOR	420,503	1.95 %
VERDIPAPIRFONDET EIKA NORGE		NOR	366,001	1.70 %
FONDSFINANS GLOBAL HELSE		NOR	352,940	1.64 %
VICAMA AS		NOR	329,530	1.53 %
DANSKE INVEST NORSKE AKSJER INST		NOR	324,514	1.51 %
SKAGEN VEKST		NOR	266,582	1.24 %
POLAR CAPITAL GLOBAL HEATHCARE GROWTH		GBR	254,537	1.18 %
RUL AS		NOR	224,451	1.04 %
BERGEN KOMMUNALE PENSJONSKASSE		NOR	200,000	0.93 %
EGELAND HOLDING AS		NOR	195,000	0.90 %
KLP AKSJENORGE INDEKS		NOR	192,480	0.89 %
WLH INVEST AS		NOR	192,014	0.89 %
A/S SKARV		NOR	150,000	0.70 %
Total 20 largest shareholders			15,237,556	70.68 %
Total other shareholders			6,320,354	29.32 %
Total number of shares			21,557,910	100.00 %



# **Photocure Group – Alternative Performance Measures**

(Information provided based on Guidelines on Alternative Performance Measures (APMs) for listed issuers by The European Securities and Markets Authority - ESMA)

Photocure reports certain performance measures that are not defined under IFRS but which represent additional measures used by the Board and management in assessing performance as well as for reporting both internally and to shareholders. Photocure believes that the presentation of these non-IFRS performance measures provides useful information which provides readers with a more meaningful understanding of the underlying financial and operating performance of the company when viewed in conjunction with our IFRS financial information.

Photocure uses the following alternative performance measures.

#### **EBITDA & EBIT**

We regard EBITDA as the best approximation to pre-tax operating cash flow and reflects cash generation before working capital changes. EBITDA is widely used by investors when evaluating and comparing businesses, and provides an analysis of the operating results excluding depreciation and amortisation. The non-cash elements depreciation and amortization may vary significantly between companies depending on the value and type of assets.

The definition of EBITDA is "Earnings Before Interest, Tax, Depreciation and Amortization".

The reconciliation to the IFRS accounts is as follows:

(all amounts in NOK 1 000)	2017 1.1-31.03	2016 1.1-31.03	2016 1.1-31.12
Gross profit Operating expenses excl amortization & depreciation	<b>33,661</b> -41,900	<b>32,481</b> -36,201	<b>134,291</b> -142,298
EBITDA	-8,239	-3,720	-8,008
Amortization & depreciation	-2,151	-1,148	-7,853
EBIT	-10,390	-4,868	-15,861

Recurring EBITDA equals EBITDA before one-off items. One-off items are accounting items of a significant and extraordinary nature. In the first quarter report Photocure has identified the write off of parts and finished goods inventory for Nedax as an on-off item, in total NOK 4.0 million.

#### Revenue growth in constant currency

Photocure's business is conducted internationally and in respective local currency. Less than 90% of the revenue is conducted in Norwegian kroner, our functional currency. Fluctuations in foreign exchange rates may have a significant impact on reported revenue in Norwegian kroner. To eliminate the translational effect of foreign exchange and to better understand the revenue development in the various regions we provide calculated revenue growth information by region and total for the company.

The average exchange rates used to translate revenues as per the reporting dates were as follows:



	2017	2016	2016
	1.1-31.03	1.1-31.03	1.1-31.12
USD (NOK per 1 USD)	8.44	8.65	8.40
EUR (NOK per 1 EUR)	8.98	9.53	9.29
DKK (NOK per 100 DKK)	120.83	127.68	124.81
SEK (NOK per 100 SEK)	94.51	102.14	98.23

# **Photocure Group – Other Measures**

#### **In-market sales**

A significant share of Photocure's sales of Hexvix/Cysview, i.e. all sales classified as partner sales and all sales in the Nordic region, goes through partners and distributors. These partners and distributors carry inventory of Hexvix/Cysview. Photocure's billing and revenue therefore does not necessarily reflect the demand from end users / hospitals at a given point in time as inventory levels may vary over time.

Furthermore, Photocure's revenue does not reflect the full value of the product in the market, as partners pay a royalty or a purchase price for the product below the price charged the end user.

To capture end user demand the company's partners and distributors report their revenue to end users in terms of number of units invoiced and in terms of revenue achieved. Photocure collects this data and consolidate to get the group total in-market sales, in units and in Norwegian kroner.

	2017	2016	2016
(all amounts in NOK 1 000)	1.1-31.03	1.1-31.03	1.1-31.12
In-market sales	65,498	60,941	241,099



# **Photocure Group – Our Products**

#### Hexvix/Cysview

Hexvix/Cysview (hexaminolevulinate hydrochloride) is a drug that is taken up selectively by cancer cells in the bladder making them glow bright pink during Blue Light Cystoscopy (BLC). BLC with Hexvix improves the detection of tumors and leads to more complete resection, less residual tumors and better management decisions.

Hexvix is the tradename in Europe, Australia and New Zealand, Cysview in the US and Canada. Photocure is commercializing Hexvix/Cysview directly in the US and the Nordic region, and has strategic partnerships for the commercialization of Hexvix/Cysview in Europe, Canada, Australia and New Zealand.

Bladder cancer ranks as the ninth most common cancer worldwide with 430,000 new cases and more than 165,000 deaths annually. 75% of all bladder cancer cases occur in men<sup>1</sup>. It has a high recurrence rate with an average of 61% in year one and 78% over five years<sup>2</sup>. Bladder cancer has the highest lifetime treatment costs per patient of all cancers<sup>3</sup>.

Bladder cancer is a costly, potentially progressive disease for which patients have to undergo multiple cystoscopies due to the high risk of recurrence. There is an urgent need to improve both the diagnosis and the management of bladder cancer for the benefit of patients and healthcare systems alike.

Bladder cancer is classified into two types, non-muscle invasive bladder cancer (NMIBC) and muscle-invasive bladder cancer (MIBC), depending on the depth of invasion in the bladder wall<sup>4</sup>. NMIBC remains in the inner layer of cells lining the bladder. These cancers are the most common (75%) of all bladder cancer cases and include the subtypes Ta, carcinoma in situ (CIS) and T1 lesions. MIBC is when the cancer has grown into deeper layers of the bladder wall. These cancers, including subtypes T2, T3 and T4, are more likely to spread and are harder to treat<sup>5</sup>.

- 1. Globocan. Incidence/mortality by population. Available at: http://globocan.iarc.fr/Pages/bar\_pop\_sel.aspx
- 2. Babjuk M, Burger M, Zigeuner R, Shariat SF, van Rhijn BW, Compérat E, et al. EAU Guidelines on non-muscle-invasive bladder cancer (Ta, T1 and CIS). Eur Urol. 2016 Guidelines Edition:1-40.
- 3. Sievert KD et al. World J Urol 2009;27:295-300
- 4. Bladder Cancer. American Cancer Society. http://www.cancer.org/acs/groups/cid/documents/webcontent/003085-pdf.pdf. Accessed April 2016
- 5. Bladder Cancer. American Cancer Society. http://www.cancer.org/acs/groups/cid/documents/webcontent/003085-pdf.pdf. Accessed April 2016

#### **Visonac**

Visonac (methyl aminolevulinate 80mg/g) is in development for the treatment of moderate to severe acne. Acne is the single most common skin disease worldwide and affects up to 85% of all 12-24 year olds. There is a high unmet medical need for patients with moderate to severe acne, where the current mainstay of treatment is oral antibiotics and/or retinoids. By avoiding the risks of increased antibiotic resistance from long term exposure and providing a better tolerated alternative than systemic retinoids, Visonac has the potential to satisfy a high unmet medical need.

#### Cevira

Cevira is in development as an intravaginal drug-device combination for photodynamic therapy of cervical persistent oncogenic human papilloma virus (HPV) infections and precancerous lesions. This treatment modality is based on our highly selective technology targeting the diseased area. Cevira is a treatment modality aiming to preserve the competence of the cervix, an improvement over surgical procedures frequently used today.



## For more information, please contact:

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