





# **Highlights for fourth quarter 2019**

(Numbers in brackets and comparisons are for the corresponding period in 2018.)

- Fourth quarter Hexvix/Cysview revenue increased 27% to NOK 58.8 million (NOK 46.3 million)
- Continued strong U.S. Cysview revenue growth with a fourth quarter increase of 51%
- The installed base of blue light cystoscopes in the U.S. was 223 at the end of the fourth quarter 2019, an increase of 66 or 42% since the same quarter 2018. The installed base includes 26 flexible cystoscopes at the end of 2019
- Signing fee of NOK 43 million (USD 5.0 million) received from Asieris for the world-wide license to develop and commercialize Cevira for the treatment of HPV induced cervical precancerous lesions
- EBITDA for the fourth quarter 2019 was NOK 54.8 million (NOK -4.1 million)
- Photocure targets U.S. revenues in the range of USD 70 million in 2023, and sees significant continued revenue growth and profit opportunities in the U.S. market beyond 2023
- In February 2020, Photocure was granted a U.S. Patent covering the use of Blue Light Cystoscopy (BLC®)
  with Hexvix/Cysview as neoadjuvant therapy in the treatment of bladder cancer in patients who are
  scheduled for a cystectomy

## **Key figures:**

Figures in NOK million	Q4 2019	Q4 2018	Change	FY 2019	FY 2018	Change
Hexvix/Cysview revenues	58.8	46.3	27 %	213.2	172.9	23 %
Other revenues	56.8	3.5		68.3	8.6	
Total revenues	115.6	49.9	132 %	281.6	181.5	55 %
Operating expenses	-52.9	-49.0	8 %	-200.1	-174.9	14 %
EBITDA excl restructuring	54.8	-4.1		58.9	-10.5	
EBITDA commercial franchise	1.6	1.3		7.3	8.4	
EBITDA development portfolio	53.2	-5.4		51.6	-18.9	
EBIT excl restructuring	51.0	-7.5		42.7	-23.7	
Restructuring expenses		-1.1			-14.2	
Net Earnings	42.5	-12.0		31.8	-36.7	
Cash & cash equivalents				125.3	106.8	

## **President & CEO Daniel Schneider comments:**

"Photocure continued its strong U.S. sales momentum and solid growth in the fourth quarter. We are making great progress in penetrating this high potential market, providing a solid platform for further short- and long-term growth. We are also very excited about the recent patent protection and will further investigate Hexvix/Cysview for its potential therapeutic effect.

Photocure will continue to develop the significant commercial opportunities in the U.S. in order to achieve our ambition to make Cysview the standard of care for bladder cancer patients.

The U.S. continues to represent the primary growth market for Photocure with a large untapped market opportunity exceeding 1 million procedures per year. Photocure targets U.S revenues in the range of USD 70 million in 2023 and sees significant continued revenue growth and profit opportunities in the U.S. market beyond 2023."



# **Operational review**

Photocure ASA (Photocure) delivers transformative solutions to improve the lives of bladder cancer patients.

Photocure is leveraging its flagship brand Hexvix/Cysview for improved detection of non-muscle invasive bladder cancer, reduction of disease recurrence and progression rates to improve cost-effective health outcomes for bladder cancer patients.

With its established specialist commercial and medical teams in the U.S. and Nordics, Photocure has a solid foundation for future growth of its breakthrough bladder cancer product, as well as exploring expansion of its product portfolio.

## **Update commercial segment**

The commercial segment continued to show improved sales and results in the fourth quarter.

Fourth quarter total Hexvix/Cysview revenue increased 27% to NOK 58.8 million (NOK 46.3 million) compared to the same quarter in 2018. The increase was driven by U.S. sales increasing by 51% compared to fourth quarter last year. Full year Hexvix/Cysview revenue increased 23% to NOK 213.2 million (NOK 172.9 million).

Other revenues include milestones related to the license agreement with Ipsen of NOK 2.5 million for the full year 2019 and NOK 3.4 million for 2018 (see note 1 to the accounts). Full year 2018 revenues also include milestone payments from Bellus Medical for Allumera totaling NOK 4.9 million. 2019 revenues include revenues from sales of Hivec, following the distribution agreement with Combat Medical.

Operating expenses, excluding depreciation and amortization, increased 14% to NOK 49.7 million (NOK 43.6 million) in the fourth quarter. Full year operating expenses, excluding depreciation and amortization, increased 20% to NOK 186.6 million (NOK 156.0 million) mainly driven by the planned increase in U.S. commercial efforts.

Fourth quarter EBITDA increased 23% to NOK 1.6 million (NOK 1.3 million). Full year EBITDA was NOK 7.3 million (NOK 8.4 million). The full year decline in EBITDA was driven by a reduction of milestone revenues from Bellus Medical of NOK 4.9 million. Fourth quarter and full year EBITDA excluding one-

off milestones from Bellus Medical increased NOK 2.8 million and NOK 3.8 million respectively.

MNOK	Q4 '19	Q4 '18	FY '19	FY '18
Nordic - Hexvix	14.5	13.5	48.2	47.0
US - Cysview	27.8	18.4	98.7	63.7
Partners	16.5	14.4	66.3	62.2
Hexvix/Cysview total	58.8	46.3	213.2	172.9
YoY growth	27 %		23 %	
Other revenues	0.3	3.5	3.2	8.6
Total revenues	59.1	49.9	216.4	181.5
YoY growth	19 %		19 %	
Gross profit	51.3	44.9	193.9	164.4
Operating expenses	-49.7	-43.6	-186.6	-156.0
EBITDA	1.6	1.3	7.3	8.4
EBITDA margin	3 %	3 %	3 %	5 %

## Hexvix®/Cysview®

Global in-market unit sales increased 4% in the fourth quarter and full year 6%. Estimated full year inmarket sales value was NOK 330 million (NOK 285 million).

#### U.S. Cysview sales

The company had a strong fourth quarter in U.S. with a revenue growth of 51% to NOK 27.8 million (NOK 18.4 million). The growth is driven by volume growth, currency weakening of the NOK against USD and price increases. In USD, the revenue growth was 39%. In-market unit growth in the fourth quarter was 34%.

Full year U.S. revenues increased 55% to NOK 98.7 million (NOK 63.7 million), with unit growth of 36%. In USD the revenue growth was 43%.

U.S. is the largest and fastest growing region for Photocure and 46% of total Hexvix/Cysview revenue was generated in U.S. in 2019 as compared to 37% in 2018. The growth is driven by added sales resources, approval of new indications, launch of the product in the bladder cancer flexible cystoscopy surveillance setting and improved reimbursement.

The introduction of Cysview in the surveillance market together with improved reimbursement has resulted in a significant growth in the installed base of permanent blue light cystoscopes. At the end of the fourth quarter the total installed base of rigid cystoscopes was 197, an increase of 32% or 48 units since year-end last year. Blue Light Cystoscopy (BLC<sup>TM</sup>) in the surveillance setting is a key priority for Photocure in the U.S. market. By the end of the fourth quarter 26 flexible cystoscopes for the surveillance cystoscopy setting have been installed.



In November, The United States Centers for Medicare and Medicaid Services (CMS) released its Final Rule for 2020 maintaining the reimbursement code (A Code) for Cysview when used in the hospital outpatient and other sites of care and the complexity adjustment code. The rule includes improved reimbursement for certain Blue Light Cystoscopy procedures effective January 1st, 2020.

#### Nordic Hexvix sales

Nordic revenues increased 7% to NOK 14.5 million (NOK 13.5 million) in the fourth quarter. Photocure's in-market unit sales in the Nordic region in fourth quarter was at level with prior year and to some extent impacted by large deliveries to hospitals in Denmark at the end of the fourth quarter.

Full year Nordic revenues increased 3% to NOK 48.2 million (NOK 47.0 million). The increase was mainly driven by currency fluctuations and price increases. In-market unit sales declined 2% from last year. A number of initiatives have been launched to improve Nordic sales performance.

#### Hexvix/Cysview partner sales

Partner revenue increased 14% to NOK 16.5 million (NOK 14.4 million) in the fourth quarter. The increase was driven by impact of currency fluctuations and increased unit sales. In-market unit sales increased 3% for the quarter, reflecting increases in markets such as Germany, Austria and Netherlands.

Full year partner revenue increased 7% to NOK 66.3 million (NOK 62.2 million). In constant currencies, revenue increased 4%. In-market unit sales increased 3%, driven mainly by Germany and France.

#### Hexvix/Cysview publications and presentations

There were multiple publications and presentations in the fourth quarter 2019 and the beginning of the first quarter 2020:

In October 2019, a study with BLC with Hexvix was presented at the 39th Congress of the Société Internationale d'Urologie held in Athens, Greece. The study objective was to evaluate the feasibility of using Blue Light flexible cystoscopy with biopsy and tumor destruction by diode laser using local anesthesia in the outpatient clinic. The authors concluded that non-muscle invasive bladder cancer can be diagnosed and treated with diode laser with local anesthesia using flexible blue light cystoscopy.

Furthermore, two abstracts on Hexvix were presented at the BLADDR 2019 congress in Paris, France in October. The presentations included the

first published data from a pre-clinical study investigating potential immunogenic treatment effects of Blue Light Cystoscopy with Hexvix. The results of the study indicate for the first time that a treatment effect could be related to immunogenic cell death responses and anti-tumor immune cell activation.

In November 2019, Photocure announced the results from a randomized controlled multi-center study with 699 bladder cancer patients presented at annual meeting of the Danish Urology Society. The study showed that use of flexible Blue Light Cystoscopy at the first follow-up after TURBT reduced the risk of tumor recurrence by 33% compared to white light alone. The results from the study were published in the journal Urology in December.

In February 2020, Photocure announced that the United States Patent and Trademark Office (USPTO) has granted US Patent No. 10,556,010 covering the use of Blue Light Cystoscopy (BLC®) with Hexvix/Cysview as neoadjuvant therapy in the treatment of bladder cancer in patients who are scheduled for a cystectomy. Photocure intends to further investigate Hexvix for its therapeutic effect and the patent is a result of Photocure's continued focus on securing intellectual property rights. This patent expires in December 2036.

#### Update development portfolio

# Cevira® – for treatment of HPV (HUMAN PAPILLOMA VIRUS) and precancerous lesions of the cervix

Cevira is a photodynamic drug-device combination product for non-surgical treatment of high-grade cervical dysplasia.

In July, the Company announced that it had entered into a License Agreement providing Asieris Meditech Co., Ltd (Asieris) with a world-wide license to develop and commercialize Cevira for the treatment of HPV induced cervical precancerous lesions.

Subsequently, Asieris has launched a global clinical development program with an initial focus on the Chinese market based on Photocure's Phase 2b data and the Phase 3 study design elements agreed with the U.S. FDA. The development for the U.S. and EU markets will follow when clinical data from the Chinese focused Phase 3 study confirms the safety and efficacy, estimated to be finished in 2022. Asieris will assume responsibility for the manufacturing of the Cevira product while Photocure retains responsibility for the manufacturing of the active pharmaceutical ingredient (API).



Under the License Agreement, Photocure has received a total signing fee of USD 5.0 million during 2019, of which USD 4 million was received in the fourth quarter. In addition, the company may receive a total of USD 18 million based upon achievement of certain clinical and regulatory milestones in China and up to USD 36 million for certain clinical and regulatory milestones in the U.S. and EU. Approval of a second indication in China, the U.S. and the EU would result in payments of up to USD 14 million. Sales milestones and royalties of 10% to 20% will apply in all markets.

# Financial review

(Numbers in brackets are for the corresponding period in 2018; references to the prior year refer to a comparison to the same period 2018, unless otherwise stated).

MNOK	Q4 '19	Q4 '18	FY '19	FY '18
Hexvix / Cysview revenues Other revenues Total revenues	58.8	46.3	213.2	172.9
	56.8	3.5	68.3	8.6
	<b>115.6</b>	<b>49.9</b>	<b>281.6</b>	<b>181.5</b>
Gross profit	107.7	44.9	259.0	164.4
Operating expenses	-52.9	-49.0	-200.1	-174.9
EBITDA before restructuring	54.8	-4.1	58.9	-10.5
Depreciation & amortization Restructuring expenses	-3.8	-3.4	-16.2	-13.2
	-	-1.1	-	-14.2
EBIT	51.0	-8.6	42.7	-37.9
Net financial items Earnings before tax Tax expenses	2.3	1.2	3.2	1.2
	<b>53.3</b>	<b>-7.3</b>	<b>45.9</b>	<b>-36.7</b>
	-10.7	-4.6	-14.1	0.0
Net earnings	42.5	-12.0	31.8	-36.7

Photocure has transformed itself from a technology-based company to a therapeutic area-focused commercial stage pharmaceutical company with a focus on bladder cancer. The allocation of resources, and hence expenses, have shifted from R&D to sales and marketing. Photocure's strategy is to maximize its commercial presence and the opportunity of its flagship brand Hexvix/Cysview in bladder cancer. In addition, the Company will continue to explore alone or in partnership with others new product opportunities that are complementary to the Company's commercial activities and expertise in bladder cancer.

The company continues to add strategic resources to its U.S. commercial organization, in line with its commercial market opportunities and strategic objectives. These resources have driven revenue growth, as well as increased sales and marketing costs.

#### Revenues

Total revenues in the fourth quarter were NOK 115.6 million, an increase of 132% from the fourth quarter

last year (NOK 49.9 million). Full year revenues were NOK 281.6 million (NOK 181.5 million), an increase of 55%.

Hexvix/Cysview revenues for the fourth quarter were NOK 58.8 million, an increase of 27% from the fourth quarter of 2018 (NOK 46.3 million). The increase was driven by strong sales in U.S. Full year Hexvix/Cysview revenues were NOK 213.2 million (NOK 172.9 million), an increase of 23%. In constant currencies, Hexvix/Cysview revenues grew approximately 18% for the year.

Other revenues in the fourth quarter were NOK 56.8 million (NOK 3.5 million). Full year other revenues were NOK 68.3 million (NOK 8.6 million).

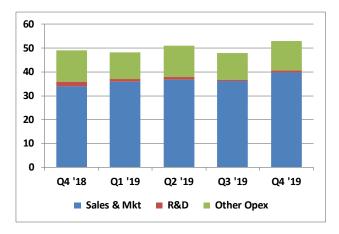
Full year other revenues are mainly impacted by the USD 5 million signing fee payment from Asieris as per the license agreement for Cevira and USD 3 million of committed and timed development milestones under the same agreement. The fees from Asieris is accounted for according to IFRS 15 (see note 1 and 8 to the accounts). Revenue recognition is based on contract value for USD 8 million based on currency exchange rates at time of executed contract.

Additionally, full year other revenues include milestones related to the license agreement with Ipsen of NOK 2.5 million (NOK 3.4 million) (see note 1 to the accounts). Furthermore, full year 2018 revenues include milestone payments from Bellus Medical for Allumera totaling NOK 4.9 million. 2019 revenues include revenues from sales of Hivec, following the distribution agreement with Combat Medical.

#### Operating expenses

Total operating expenses, before restructuring and excluding depreciation and amortization, were NOK 52.9 million (NOK 49.0 million) in the fourth quarter, an increase of 8%. Full year, the operating expenses increased 14% to NOK 200.1 million (NOK 174.9 million).

The YoY increase in operating expenses was driven by planned strategic investments in U.S. commercial operations. Furthermore, the company has had business development expenses during the year, particularly related to Cevira.



Fourth quarter research and development (R&D) costs were NOK 1.0 million (NOK 2.0 million), a reduction of 50%. Full year R&D costs were NOK 3.6 million (NOK 9.3 million), a reduction of 61%. The remaining R&D costs relate mainly to regulatory work and maintenance and expansion of Photocure's intellectual property.

Sales and marketing costs increased 17% to NOK 39.7 million (NOK 33.9 million) in the fourth quarter. Sales and marketing costs full year were NOK 148.6 million (NOK 121.2 million). The increase of 23% was in line with Photocure's strategic plan and was mainly driven by activities in U.S.

Fourth quarter other operating expenses, which include supply chain, business development, and general/administration, decreased 6% to NOK 12.2 million (NOK 13.1 million). Full year other operating expenses increased 8% to NOK 47.9 million (NOK 44.3 million). The main reason for the increase was business development expenses particularly related to Cevira.

#### Financial results

EBITDA before restructuring was NOK 54.8 million (NOK -4.1 million) for the fourth quarter. Full year EBITDA before restructuring was NOK 58.9 million (NOK -10.5 million). Currency translation had no significant impact on the fourth quarter results and approximately 1 million negative impact on the full year results.

EBITDA before restructuring in the commercial segment was full year NOK 7.3 million (NOK 8.4 million). The development portfolio EBITDA before restructuring full year was NOK 51.6 million (NOK - 18.9 million).

Full year depreciation and amortization was NOK 16.2 million (NOK 13.2 million). The main cost item was the amortization on the investments in intangible assets related to the Phase 3 market expansion trial

for Cysview. The increase from prior year was mainly driven by the adoption of IFRS 16 as the amortization of the right-of-use assets replace office rental costs as reported operating lease (see note 3 to the accounts).

Net financial items for the full year were NOK 3.2 million (NOK 1.2 million).

Photocure had a net profit before tax of NOK 53.3 million in the fourth quarter (net loss of NOK 7.3 million) and a full year net profit before tax of NOK 45.9 million (net loss of NOK 36.7 million). Net profit after tax was NOK 42.5 million for the fourth quarter (net loss of NOK 12.0 million) and full year NOK 31.8 million (net loss of NOK 36.7 million).

#### Cash flow and statement of financial position

Net cash flow from operations was positive NOK 30.4 million in the fourth quarter (NOK 11.2 million) and full year NOK 20.7 million (negative NOK 24.1 million). This improvement was mainly driven by the signing fee paid by Asieris and the improved operating results. The impact from changes to the working capital full year was negative NOK 7.1 million (positive NOK 1.4 million). Payments of NOK 3.2 million in the first quarter of 2019 related to the 2018 restructuring, is included in the working capital changes. Other operational items include the Net Present Value (NPV) of the unpaid part of the milestone revenue from Asieris as of December 31, 2019 totaling NOK 23.0 million.

Net cash flow from investments full year was positive NOK 0.6 million (negative NOK 1.1 million).

Full year cash flow from financing was negative NOK 2.8 million, driven by payment of lease liability (IFRS 16, see note 3).

Fourth quarter net change in cash was positive NOK 29.4 million (positive NOK 14.0 million). Full year net change in cash was positive NOK 18.5 million (negative NOK 22.5 million). Cash and cash equivalents were NOK 125.3 million at the end of the year.

Shareholders' equity was NOK 208.6 million at the end of the year, an equity ratio of 81%.

As of 31 December 2019, Photocure held 16,624 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 commercial risk, financial



risk, market risk, legal and regulatory 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 2018.

## **Outlook**

Photocure delivers transformative solutions which improve the lives of bladder cancer patients. Based on experience and the performance of the breakthrough bladder cancer product Hexvix/Cysview, Photocure has embarked on a stepwise approach for continued growth. Photocure sees significant long-term potential in the global

bladder cancer market and has a defined growth strategy:

- Accelerating Drive the breadth and depth of Hexvix/Cysview usage in key accounts
- Expanding Generate sales in new geographies and product enhancements
- Acquiring Products used in the management of bladder cancer patients
- Transforming Partner and in-license assets to strengthen the bladder cancer portfolio

The U.S. continues to represent the primary growth market for Photocure with a large untapped market opportunity exceeding 1 million procedures per year.

Based on the outlook and strategic opportunities, Photocure targets U.S. revenues in the range of USD 70 million in 2023, and sees significant continued revenue growth and profit opportunities in the U.S. market beyond 2023.

# The Board of Directors and CEO Photocure ASA

Oslo, 26 February 2020

Jan Hendrik Egberts	Einar Antonsen	Johanna Holldack
Chairperson	Director	Director
Gwen Melincoff	Tom Pike	Tove Lied Ringvold
Director	Director	Director
Grannum R. Sant Director		Daniel Schneider President and CEO



# Photocure Group Accounts for fourth quarter and preliminary full year 2019

# **Photocure Group – Statement of comprehensive income**

		2019	2018	2019	2018
(all amounts in NOK 1,000 except per share data)	Note	Q4	Q4	1.1 - 31.12	1.1-31.12
Sales revenues		59,115	46,526	213,908	173,237
Signing fees and milestone revenues	8	56,450	3,340	67,648	8,273
Total revenues		115,564	49,866	281,556	181,510
Cost of goods sold		-7,845	-4,965	-22,512	-17,147
Gross profit		107,720	44,901	259,045	164,363
Indirect manufacturing expenses	4	-2,801	-1,626	-10,965	-10,252
Research and development expenses	4	-3,520	-4,467	-13,644	-19,145
Marketing and sales expenses	4	-39,738	-33,928	-148,738	-121,301
Other operating expenses	4	-10,649	-12,389	-42,961	-37,370
Total operating expenses recurring		-56,709	-52,409	-216,308	-188,066
EBIT before restructuring		51,011	-7,508	42,737	-23,703
Restructuring		-	-1,066	-	-14,199
EBIT including restructuring		51,011	-8,574	42,737	-37,902
Financial income		4,471	1,590	7,978	3,652
Financial expenses		-2,217	-356	-4,813	-2,464
Net financial profit/loss(-)		2,254	1,234	3,165	1,188
Profit/loss(-) before tax		53,265	-7,340	45,901	-36,715
Tax expenses	5	-10,725	-4,630	-14,070	6
Net profit/loss(-)		42,540	-11,970	31,831	-36,709
Other comprehensive income		-303	106	-197	-308
Total comprehensive income		42,237	-11,864	31,634	-37,017
Net profit/loss(-) per share, undiluted	6	1.95	-0.55	1.46	-1.70
Net profit/loss(-) per share, diluted	6	1.95	-0.55	1.46	-1.70



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

-			
(Amounts in NOK 1,000)	Note	31.12.2019	31.12.2018
Non-currrent assets			
Intangible assets	7	11,605	22,502
Machinery & equipment		2,040	2,141
Right-of-use assets	3	7,008	-
Deferred tax asset	5	38,345	52,377
Long term receivables	8	11,478	-
Contract costs		0	747
Total non-current assets		70,476	77,767
Current assets			
Inventories		16,410	18,582
Accounts receivable	8	24,206	20,371
Other receivables		20,940	7,643
Cash and short term deposits	9	125,320	106,833
Total current assets		186,876	153,429
Total assets		257,352	231,196
Equity and liabilities			
Equity			
Share capital	10	10,898	10,890
Other paid-in capital		64,261	63,656
Retained earnings		133,431	101,797
Shareholders' equity		208,590	176,342
Long-term liabilities			
Pension liability		3,088	2,401
Lease liability	3	6,948	-
Total long-term liabilities		10,036	2,401
Current liabilities		38,725	45,389
Contract liabilities		0	7,064
Total liabilities		48,762	54,854
Total equity and liabilities		257,352	231,196

# **Photocure Group – Changes in equity**

(Amounts in NOK 1,000)	2019 Q4	2018 Q4	2019 1.1 - 31.12	2018 1.1-31.12
Equity at end of prior period			176,342	218,080
Adjustments initial applications of IFRS 16, 9 and 15			0	-10,746
Adjusted equity beginning of period	166,353	182,621	176,342	207,334
Capital increase		5,597	614	6,339
Share-based compensation (share options employees)	-	-12	-	63
Own shares	-		-	-377
Comprehensive income	42,237	-11,864	31,634	-37,017
Equity at end of period	208,590	176,342	208,590	176,342



# **Photocure Group – Cash flow statement**

	2019	2018	2019	2018
(Amounts in NOK 1,000)	Q4	Q4	1.1 - 31.12	1.1-31.12
Profit/loss(-) before tax	53,265	-7,340	45,901	-36,715
Depreciation and amortisation	3,771	3,431	16,213	13,211
Share-based compensation	-	-12	-	63
Net interest income	-375	-149	-1,696	-1,125
Changes in contract receivable	-22,956		-22,956	
Changes in working capital	3,110	11,911	-7,086	1,416
Other operational items	-6,393	3,339	-9,722	-976
Net cash flow from operations	30,421	11,180	20,654	-24,124
Net investments in fixed assets	-173	-528	-770	-1,630
Intangible asset expenditures	-233	-	-316	-559
Received interest payments	375	149	1,696	1,125
Cash flow from investments	-31	-379	610	-1,063
Share capital increase employees	-	6,339	614	6,339
Reclassification and paid long-term liability	-	-3,136	-	-3,310
Payment lease liability	-976	-	-3,391	-
Buy back own shares	-	-	-	-377
Cash flow from financing activities	-976	3,203	-2,777	2,652
Net change in cash during the period	29,414	14,005	18,487	-22,535
Cash & cash equivalents at beginning of period	95,906	92,828	106,833	129,368
Cash & cash equivalents at end of period	125,320	106,833	125,320	106,833



# Notes to the accounts for fourth quarter and full year 2019

## 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 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 2018 (the Annual Financial Statements) as they provide an update of previously reported information.

The Group's financial statements include from 2019 the principles and presentation related to the implementation of IFRS 16. Changes to significant accounting policies are described below and in Note 3.

The interim report has not been subject to an audit. The Board of Directors approved the interim financial statements on 26 February 2020.

Photocure ASA 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.

#### Changes in significant accounting policies

#### **IFRS 16**

IFRS 16 introduces a single, on-balance sheet accounting model for lessees. The standard is effective for annual period beginning on or after 1 January 2019. The adoption of IFRS 16 do not have a significant impact on Photocure's statement of financial position as future lease payments under existing office lease contracts are limited, ref. note 14 to the 2018 annual financial statements. The initial calculation of the Right-of-use assets and corresponding leasing liabilities as per 1 January 2019 related to office lease contracts amounts to NOK 10.4 million.

#### Important accounting valuations, estimates and assumptions

#### **IFRS 15**

For the current contract with Ipsen Pharma, the only identified distinct performance obligation is delivery of goods. The contract term was estimated to be equal to the expiry date of the patents in the relevant market areas that was medio September 2019 for main countries. Received up-front payment related to this contract has been deferred and has been recognized as revenue in line with transfer of control of the goods.

For the contract with Asieris MediTech Co. Ltd entered into in July 2019, two performance obligations are identified; a license for Cevira and delivery of active substance. The license is a right to use Photocure's intellectual property as it existed at the contract date. The total transaction price is allocated between the two performance obligations based on the relative stand-alone selling price. The transaction price allocated to the license consist of signing fee, different milestone payments and sales-based royalty payments. The part of the transaction price related to



milestone payments are estimated as the most likely amount but constrained which currently means that these revenues will be recognized if and when the relevant milestone are achieved. Sales based royalty is recognized when the subsequent sales occur. Revenue for the sale of goods is recognized when the customer takes control of the goods, which is at the time of shipment.

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 judgement 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 milestone and royalties from a licence partner. Development Portfolio includes development of commercial products and pipeline products.

1 Jan - 31 December 2019		Commercial	Products		Development Products				
	Hexvix/0	Cysview							
(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	146,877	66,337	694	213,909	-	-	-	213,909	
Milestone revenues	-	2,534	-	2,534	-	65,115	65,115	67,648	
Cost of goods sold	-9,089	-13,086	-337	-22,512	-	-	-	-22,512	
Gross profit	137,788	55,785	357	193,930	-	65,115	65,115	259,045	
Gross profit of sales %	94 %	80 %	51 %	89 %				89 %	
R&D	-	-	-	-	-1,822	-1,822	-3,644	-3,644	
Sales & marketing	-136,411	-9,269	-	-145,679	-903	-1,988	-2,891	-148,570	
Other & allocations	-19,221	-19,176	-2,516	-40,913	-2,423	-4,545	-6,968	-47,882	
Operating expenses	-155,631	-28,445	-2,516	-186,593	-5,148	-8,355	-13,503	-200,096	
EBITDA	-17,844	27,340	-2,159	7,337	-5,148	56,759	51,612	58,949	

1 Jan - 31 December 2018		Commercia	mmercial Products Development Products					
	Hexvix/Cysview							
(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	110,725	62,209	303	173,237	-	-	-	173,237
Milestone revenues	-	3,378	4,895	8,273	-	-	-	8,273
Cost of goods sold	-6,562	-10,514	-71	-17,147	-	-	-	-17,147
Gross profit	104,163	55,073	5,127	164,363	-	-	-	164,363
Gross profit of sales %	94 %	83 %	77 %	90 %				90 %
R&D	-	-	-	-	-2,363	-6,962	-9,325	-9,325
Sales & marketing	-113,961	-6,258	-	-120,219	-	-994	-994	-121,213
Other & allocations	-18,123	-17,630	-	-35,753	-1,357	-7,206	-8,563	-44,317
Operating expenses	-132,084	-23,888	-	-155,972	-3,721	-15,162	-18,883	-174,855
EBITDA	-27,921	31,185	5,127	8,391	-3,721	-15,162	-18,883	-10,492



Q4 2019		Commercia	l Products		Devel	opment Pro	ducts		
	Hexvix/0	Cysview							
(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	42,301	16,468	346	59,116	-	-	-	59,116	
Milestone revenues	-	-	-	-	-	56,450	56,450	56,450	
Cost of goods sold	-3,066	-4,615	-165	-7,845	-	-	-	-7,845	
Gross profit	39,235	11,854	181	51,270	-	56,450	56,450	107,720	
Gross profit of sales %	93 %	72 %	52 %	87 %				87 %	
R&D	-	-	-	-	-532	-488	-1,020	-1,020	
Sales & marketing	-35,887	-2,960	-	-38,847	-239	-598	-837	-39,684	
Other & allocations	-5,532	-4,667	-626	-10,825	-601	-808	-1,409	-12,234	
Operating expenses	-41,419	-7,627	-626	-49,672	-1,372	-1,894	-3,266	-52,938	
EBITDA	-2,183	4,227	-445	1,599	-1,372	54,555	53,183	54,782	

Q4 2018		Commercia	Products	icts Development Products					
	Hexvix/Cysview								
(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	31,959	14,385	182	46,526	-	-	-	46,526	
Milestone revenues	-	845	2,495	3,340	-	-	-	3,340	
Cost of goods sold	-2,023	-3,054	112	-4,964	-	-	-	-4,964	
Gross profit	29,937	12,176	2,789	44,902	-	-	-	44,902	
Gross profit of sales %	94 %	79 %	161 %	89 %				89 %	
R&D	-	-	-	-	-669	-1,343	-2,012	-2,012	
Sales & marketing	-32,213	-1,401	-	-33,613	-	-284	-284	-33,897	
Other & allocations	-5,047	-4,946	-	-9,992	-497	-2,581	-3,078	-13,070	
Operating expenses	-37,259	-6,346	-	-43,605	-1,166	-4,208	-5,374	-48,979	
EBITDA	-7,322	5,830	2,789	1,297	-1,166	-4,208	-5,374	-4,077	

# Note 3 – Changes in significant accounting policies

The Group adopted IFRS 16 "Leases" from 1 January 2019. The effect of initially applying this standard is mainly attributed to the following:

- The adoption of IFRS 16 have an impact on Photocure's recognition of operating expenses as the amortization
  of the right-of-use assets replace office rental costs as reported operating lease.
- The lease liability is measured at the present value of the lease payments that are not paid at the commencement, discounted using the Groups incremental borrowing rate as the discount rate.

The Group has adopted IFRS 16 using the cumulative effect method and accordingly, the information presented for 2018 has not been restated.

The following table summarizes the impacts of transition to IFRS 16 at 1 January 2019 and 31 December 2019.



Impacts on transition	Discount	01.01.2019	31.12.2019
(Amounts in NOK 1 000)	rate	Value	Value
Right-of-use assets Norway	2.60 %	6,393	3,996
Right-of-use assets US	5.20 %	3,958	3,013
Total Lease Assets		10,351	7,008
Lease liability		-10,351	-6,948
Total non-current liabilities	-	-10,351	-6,948

Impacts for the period	01.01 31.12.19
(all amounts in NOK 1 000)	Value
Amortisation of assets	3,429
Interest expenses	236
Costs IFRS 16	3,664

# Note 4 – Income statement classified by nature

	2019	2018
(Amounts in NOK 1 000)	1.1-31.12	1.1-31.12
Sales revenues	213,908	173,237
Signing fees and milestone revenues	67,648	8,273
Cost of goods sold	-22,512	-17,147
Gross profit	259,045	164,363
Payroll expenses	-123,109	-99,369
R&D costs excl. payroll expenses/other operating exp.	-1,761	-3,742
Ordinary depreciation and amortisation	-16,213	-13,211
Other operating expenses	-75,225	-71,744
Total operating expenses recurring	-216,308	-188,066
EBIT before restructuring	42,737	-23,703



#### Note 5 – Tax

(Amounts in NOK 1 000)	31.12.2019	31.12.2018
Income tax expense		
Tax payable	-38	533
Changes in deferred tax	-14,032	-526
Total income tax expense	-14,070	6
Too be a control of the		
Tax base calculation		
Profit before income tax	61,375	1,654
Permanent differences	1,988	801
Temporary differences	-6,145	-8,063
Change in tax loss carried forward	-57,218	5,609
Tax base	0	0
Temporary differences:		
Total	-104 110	-97,966
	-104,110	,
Tax loss carried forward	278,404	336,041
Net temporary differences	174,293	238,075
Deferred tax benefit	174,293	238,075
Deferred tax asset	38,345	52,377

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

The calculation of deferred tax asset 31 December 2019 and 31 December 2018 is based on a tax rate of 22%.

The parent company has recognized a deferred tax asset regarding net temporary differences. Accumulated tax asset in the parent company at the end of December 2019 is NOK 38.3 million compared to NOK 52.4 million at end of 2018. There is no expiry on losses to be carried forward in Norway. The basis for recognition of a tax asset in Norway are the predicted future profit according to the business plan for all major markets and that temporary differences for the coming years will be reversed. 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.

For further information Photocure refer to the consolidated financial statements for the year ended 31 December 2018 note 12.

## Note 6 – Earnings per share

Earnings per share are calculated on the basis of the profit/loss for the year after tax but excluding other comprehensive items. The result is divided by a 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 by the number of employee options that can be exercised. Antidilution effects are not taken into consideration.



(Figures indicate the number of shares)	2019 1.1-31.12	2018 1.1-31.12
Issued ordinary shares 1 January	21,779,008	21,557,910
Effects of share options excercised	-	17,781
Effect of treasury shares	-15,839	-9,616
Effect of shares issued	14,855	16,905
Weighted average number of shares	21,778,024	21,582,980
Effect of outstanding share options	56,784	47,512
Weighted average number of diluted shares	21,834,808	21,630,492
Earnings per share in NOK	1.46	-1.70
Earnings per share in NOK diluted	1.46	-1.70

#### Note 7 - Fixed Assets

	Machinery &	
(Amounts in NOK 1 000)	equipment	Intangibles
Net book value 31.12.18	2,141	22,502
Net investments 31.12.19	722	1,064
Depreciation and amortization	-823	-11,961
Net book value 31.12.19	2,040	11,605

Photocure has carried out a clinical study in US for the approved product Cysview in order to file a supplemental NDA. Related to this study Photocure has capitalized, net after amortization, NOK 19.6 million as of end December 2018 and NOK 9.6 million as of 31 December 2019. The investment is amortized on a straight-line basis in the profit and loss from the start of the project and over the remaining patent period for the approved product and indication.

The remaining intangible assets consist of capitalized software and project for new homepage.

#### Note 8 - Contract revenue and receivable

Photocure has entered into a license agreement with Asieris Meditech Co., Ltd with a world-wide license to develop and commercialize the pipeline product Cevira® for the treatment of HPV. Under the agreement Photocure has received signing fees of USD 5 million in 2019 and will receive development- and approval milestones. Based on IFRS 15 Photocure has recognized a distinct right to use license for Asieris as of July 2019 of USD 8 million. The net present value of the unpaid part of contract revenue as of December 31, 2019 is split in an equal short term and long term receivable balance of NOK 23 million in total.

#### Note 9 - 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	89,671	-	-	89,671
Total	89,671	-	-	89,671

# Note 10 – 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 2018	21,779,008	NOK 0.50	10,889,504
Share capital at 31 December 2019	21,796,387	NOK 0.50	10,898,194
Treasury shares:			
Holdings of treasury shares at 31 December 2018	14,930		7,465
Buy-back of shares	1,694	NOK 0.50	847
Buy-back of restricted shares	-	NOK 0.50	-
Holdings of treasury shares at 31 December 2019	16,624		8,312

The table below indicates the status of authorizations at 31 December 2019:

(Figures indicate the number of shares)	Purchase, treasury shares	Ordinary share issue	Employee share issues
Authorisation issued at the General Meeting on 9 May 2019	2,179,638	2,179,638	500,000
Share issues after the General Meeting on 9 May 2019	-	-	-
Purchase of treasury shares	-1,694	-	-
Remaining under authorisations at 31 December 2019	2,177,944	2,179,638	500,000

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 December 2019:



Name	Position	No. of shares	No. of restricted shares	No. of subscription rights
Daniel Schneider	President & CEO	15,000	18,353	-
Erik Dahl	Chief Financial Officer	3,500	7,133	25,500
Geoffrey Coy	Head, US Cancer Commercial Operations	-	-	-
Grete Hogstad	Vice President Strategic Marketing	13,878	5,566	21,000
Kari Myren	Head of Global Medical Affairs and Clin. Dev.	=	962	-
Espen Njåstein	Head, Nordic Cancer Commercial Operations	8,378	3,649	27,800
Gry Stensrud	Vice President Tech. Dev. & Operations	1,845	5,344	26,300
Jan H. Egbert	Chairperson of the board	14,500	-	-
Einar Antonsen	Board member	13,500	-	-
Gwen Melincoff	Board member	1,000	-	-
Tom Pike	Board member	3,400	-	<u>-</u>

The restricted shares have a three year lock-up period and are subject to other customary terms and conditions for employee incentive programs.

# Note 11 – Share options

At 31 December 2019, employees in Photocure had the following share option schemes:

Year of allocation	2017	2016
Option programme	2017	2016
Number	43,000	188,700
Exercise price (NOK)	38.06	40.15
Date of expiry (31 December)	2021	2020

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

	31.12.2019		31.12.2018	
		Average exercise price		Average exercise price
	No. of shares	(NOK)	No. of shares	(NOK)
Outstanding at start of year	381,868	37.02	737,669	35.53
Allocated during the year	-	-	-	-
Become invalid during the year	-	-	170,367	38.02
Exercised during the year	150,168	32.78	185,434	30.18
Expired during the year	-	-	-	-
Outstanding at end of period	231,700	39.76	381,868	37.02
Exercisable options at end of period	231,700	39.76	367,533	36.98



# Note 12 - Shareholders

Overview of the major shareholders at 31 December 2019:

Major Shareholders	Citizen	Туре	# Shares	%
HIGH SEAS AS	Norway	Ordinary	2,220,000	10.2 %
VERDIPAPIRFONDET KLP AKSJENORGE	Norway	Ordinary	700,000	3.2 %
RADIUMHOSPITALETS FORSKNINGSSTIFT.	Norway	Ordinary	653,319	3.0 %
VERDIPAPIRFONDET FONDSFINANS NORGE	Norway	Ordinary	560,000	2.6 %
MYRLID AS	Norway	Ordinary	522,000	2.4 %
NORDNET LIVSFORSIKRING AS	Norway	Ordinary	521,276	2.4 %
KOMMUNAL LANDSPENSJONSKASSE	Norway	Ordinary	500,000	2.3 %
MP PENSJON PK	Norway	Ordinary	367,209	1.7 %
VICAMA AS	Norway	Ordinary	329,530	1.5 %
DANSKE BANK A/S	Denmark	Nominee	322,769	1.5 %
VINTERSTUA AS	Norway	Ordinary	260,402	1.2 %
BEELINE AS	Norway	Ordinary	239,894	1.1 %
BNP PARIBAS SECURITIES SERVICES	Australia	Nominee	232,309	1.1 %
NORDNET BANK AB	Sweden	Nominee	206,849	0.9 %
SKØIEN AS	Norway	Ordinary	200,000	0.9 %
KRISTIANRO AS	Norway	Ordinary	181,087	0.8 %
EGELAND HOLDING AS	Norway	Ordinary	180,000	0.8 %
JPMORGAN CHASE BANK N.A., LONDON	UK	Nominee	167,890	0.8 %
LEHRE HOLDING AS	Norway	Ordinary	164,390	0.8 %
BILLINGTON, ERIK	Norway	Ordinary	162,000	0.7 %
Total 20 largest shareholders			8,690,924	39.9 %
Total other shareholders			13,105,463	60.1 %
Total number of shares			21,796,387	100.0 %



# **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 the IFRS financial information.

Photocure uses the following alternative performance measures.

#### **EBITDA & EBIT**

Photocure regards EBITDA as the best approximation to pre-tax operating cash flow and reflects cash generation before working capital changes and capex. 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)	2019 Q4	2018 Q4	2019 1.1-31.12	2018 1.1-31.12
Gross profit Operating expenses excl amortization & depreciation	<b>107,720</b> -52,938	<b>44,901</b> -48,978	<b>259,045</b> -200,095	<b>164,363</b> -174,855
EBITDA before restructuring	54,782	-4,077	58,950	-10,492
Amortization & depreciation	-3,771	-3,431	-16,213	-13,211
EBIT before restructuring	51,011	-7,508	42,737	-23,703

Recurring EBITDA equals EBITDA before restructuring. In 2018 Photocure incurred NOK 14.2 million in restructuring costs. Photocure choose to measure before restructuring costs because adjustments of these items give a better basis for an evaluation of future results.

## Revenue growth in constant currency

Photocure's business is conducted internationally and in respective local currency. Less than 10% of the revenue is conducted in Norwegian kroner, Photocure's 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 Photocure provides 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:



	2019	2018	2019	2018
	Q4	Q4	1.1-31.12	1.1-31.12
USD (NOK per 1 USD)	9.11	8.44	8.80	8.13
EUR (NOK per 1 EUR)	10.09	9.63	9.85	9.60
DKK (NOK per 100 DKK)	135.08	129.10	131.93	128.80
SEK (NOK per 100 SEK)	94.81	93.39	93.05	93.63

# **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.

	2019	2018	2019	2018
(all amounts in NOK 1 000)	Q4	Q4	1.1-31.12	1.1-31.12
In-market sales	87,083	73,189	330,261	284,809



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## Please visit our websites for information about our products:

www.photocure.com
www.hexvix.com (Currently under construction)
www.cysview.com