

# Photocure

Financial update

## A strong quarter in the US

Photocure announced results for Q117 with 9% growth for the Hexvix/Cysview franchise compared to Q116. The US was a major driver, up 32% to NOK10m, though the Nordics fell by 4% to NOK9.7m due to currency and weakness in Denmark. Importantly, the company also recently announced that its Phase III trial in the bladder cancer surveillance market was successful, which should enable it to receive marketing authorisation in that market.

Year end	Revenue (NOKm)	PBT* (NOKm)	EPS* (NOK)	DPS (NOK)	P/E (x)	Yield (%)
12/15	134.7	(17.4)	(0.82)	0.0	N/A	N/A
12/16	143.6	12.8	0.59	0.0	46.3	N/A
12/17e	145.5	(48.9)	(2.26)	0.0	N/A	N/A
12/18e	242.5	5.8	0.26	0.0	105.0	N/A

Note: \*PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

## US sales continue to be strong

Sales in the US increased 32% to NOK10.0m driven mainly by volume growth and price increases, though there was also a minor currency headwind. Unit sales increased 28% and six additional units were installed over the quarter, bringing the total installed base to 89. The company is in the process of increasing the size of the US salesforce, which may enable it to maintain the fast pace of growth and take advantage of the recent Phase III data in the surveillance setting.

## Surveillance trial data potentially transformational

Data from the 304-patient Phase III trial of Hexvix/Cysview in the surveillance setting showed that the product increased detection of patients with recurrence and that 21.5% ( $p < 0.0001$ ) of the patients with recurrence had one that was only detected with Hexvix/Cysview. Hexvix/Cysview sales may have significant upside if the product successfully expands into the US bladder cancer surveillance market, which has 1.2m procedures per year, compared to its current market of 250,000 transurethral resection of the bladder (TURB) procedures.

## Nordic segment continues to struggle

2016 was a relatively difficult year for Photocure in the Nordic region due to staffing issues on its salesforce and the franchise only grew 1% over the course of the year. Q117 Nordic revenues fell 4% to NOK9.7m (though on a constant currency basis they were up 1%) and in-market unit sales were down 8%. Results were especially weak in Denmark due to the reorganisation of hospitals in the Copenhagen region.

## Valuation: NOK947m or NOK44 per share

We have adjusted our valuation to NOK947m or NOK44 per basic share, from NOK943m or NOK44 per basic share, mainly due to rolling over our NPV model to Q117. We expect approval for the US surveillance market and profitability in 2018. The company ended Q117 with NOK155m in cash, and we do not expect it to require further financing.

## Pharma & biotech

6 June 2017

**Price** **NOK27.30**
**Market cap** **NOK590m**

NOK8.47/US\$

Net cash (NOKm) at 31 March 2017 155

Shares in issue 21.6m

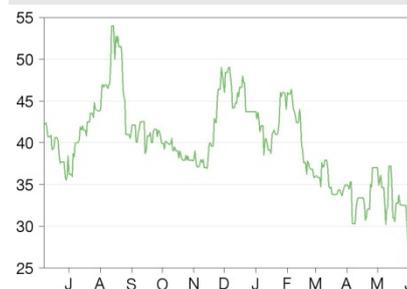
Free float 85%

Code PHO

Primary exchange Oslo

Secondary exchange N/A

## Share price performance



% 1m 3m 12m

Abs (21.1) (23.7) (36.1)

Rel (local) (21.7) (23.3) (39.3)

52-week high/low NOK54.0 NOK26.7

## Business description

Photocure specialises in photodynamic therapy. Its bladder cancer imaging product is sold as Hexvix in Europe and Cysview in the US. Photocure handles the marketing in Nordic countries and the US, while Ipsen is its marketing partner in the EU. Cevira is a Phase III-ready product for HPV-related diseases of the cervix and Visonac is a Phase III-ready product for acne.

## Next events

Surveillance market launch 2018

## Analysts

Maxim Jacobs +1 646 653 7027

Nathaniel Calloway +1 646 653 7036

[healthcare@edisongroup.com](mailto:healthcare@edisongroup.com)
[Edison profile page](#)

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## First quarter results

Photocure reported total revenue of NOK36.5m for Q117, representing 5% growth over Q116. This was driven by 9% year-on-year growth of revenues from Hexvix/Cysview (NOK36.5m vs NOK33.5m), offset by a lack of milestone revenue compared to NOK1.3m in Q116.

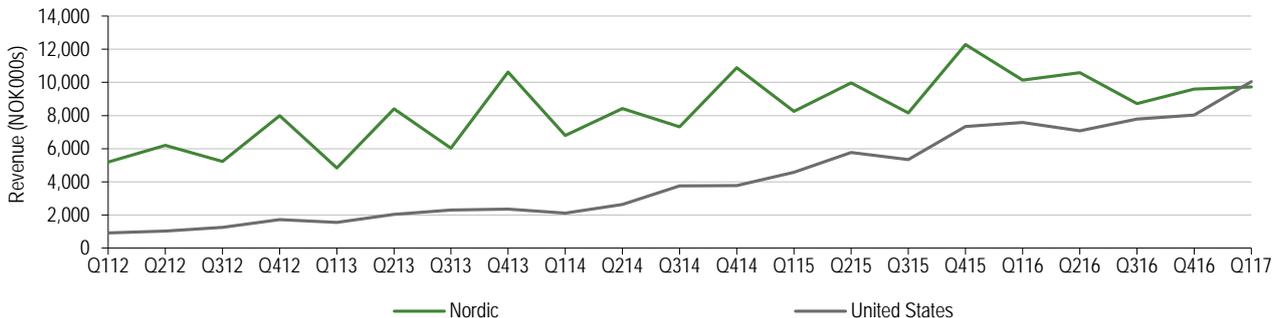
**Exhibit 1: Q117 Hexvix/Cysview sales**

	Revenue (NOKm)	Y-o-y	Q-o-q	Units	Y-o-y	Q-o-q
Hexvix sales Nordic	9,731	-4%	1%	2,271	-8%	-7%
Cysview sales US	10,041	32%	25%	1,276	28%	22%
Total own sales	19,772	12%	12%	3,547	2%	2%
Partner sales	16,742	6%	20%	11,908	12%	10%
Total Hexvix/Cysview	36,514	9%	16%	15,455	9%	8%

Source: Photocure

End user unit sales were especially strong in the US (up 28%), which was driven by an increase in the number of permanent blue light cystoscopes installed and by an increase in the usage per centre. The ongoing expansion of the US salesforce may help improve the already positive dynamics there even further. Nordic sales were hampered by weak results across Scandinavia but mainly due to a reorganisation of hospitals in the Copenhagen region. Growth in partnered areas was hampered by the delayed placement of scopes and reimbursement issues in the new markets of Australia and Canada.

**Exhibit 2: Hexvix/Cysview in-market sales**



Source: Photocure

SG&A for Q1 was slightly higher than recent quarters at NOK33.5m (compared to NOK30.3m in Q4). SG&A will likely increase in 2017 and 2018 due in large part to an increase in the number of salespeople in the US. This will enable them to penetrate additional metropolitan areas and lay the groundwork in preparation for the surveillance market launch. R&D expenses were up (to NOK8.5m from NOK5.0m), mainly due to a NOK4.0m write-down of Nedax lamp inventory (the lamp is associated with the Visonac product).

## Improving bladder cancer surveillance

Photocure presented new clinical results of Hexvix/Cysview at the American Urological Association (AUA) meeting on 14 May 2017. The results are from the Phase III clinical study measuring the utility of Hexvix/Cysview for the ongoing surveillance of patients with non-muscle invasive bladder cancer (NMIBC). After diagnosis, patients with NMIBC typically undergo a TURB procedure, in which tumours are resected using a cystoscope. Hexvix/Cysview is already approved for use during TURB procedures to improve the identification of lesions for removal. These patients are then

followed with routine surveillance for recurrence, which is high with NMIBC. The AUA recommends surveillance every three to six months for the first three years after diagnosis and yearly thereafter.

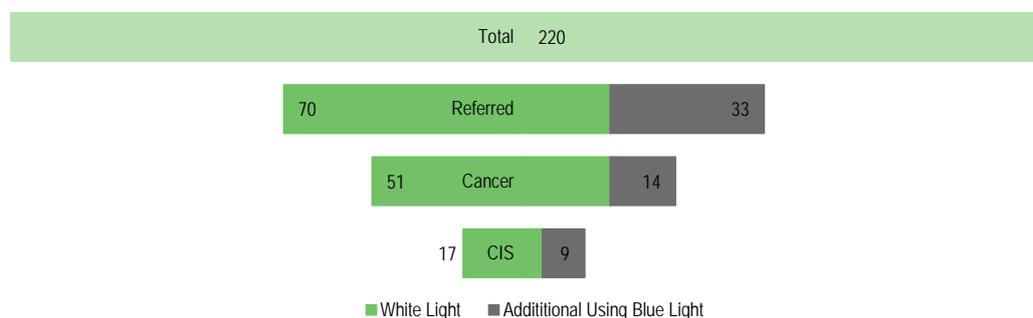
The clinical trial enrolled 304 patients at 17 institutions in the US. It only enrolled patients with a high probability of recurrence as identified by having multiple tumours, a previous recurrence, and/or high-grade tumours in previous procedures. Patients on the study underwent both blue light and white light cystoscopy and the ability of the two techniques to identify recurrence events was compared. The primary end point of the trial was the number of patients with recurrences who were identified using Hexvix/Cysview who were missed with white light cystoscopy. In addition to the experimental portion of the trial, 68 patients were included for training purposes to acclimatise physicians to blue light cystoscopy.

A total of 220 patients were in the experimental portion of the trial and available for evaluation. From this population, 103 patients were referred to the operating room for a TURB procedure based on initial surveillance cystoscopy, and 65 had a confirmed recurrence. 14 patients (21.5%  $p < 0.0001$ ) were referred to the operating room using Hexvix/Cysview and would have been missed using white light cystoscopy alone. This is significant evidence that Hexvix/Cysview can improve the surveillance in this population. Moreover, of these 65 patients with recurrence, almost half (30 patients, 46.2%) had additional lesions detected using Hexvix/Cysview over white light cystoscopy alone. In particular, Hexvix/Cysview improved the identification of carcinoma in situ (CIS). CIS is a small flat lesion in the early stages of its growth before it is generally considered a tumour with high risk of progression. Of the patients on the trial, 26 had confirmed CIS, of which nine (34.6%,  $p < 0.0001$ ) were diagnosed with Hexvix/Cysview and would have otherwise been missed.

The use of Hexvix/Cysview did substantially increase the number of false positive diagnoses of recurrence. It doubled the number of patients from 19 to 38 (8.6% to 17.2%) that were referred for TURB who turned out to not have a malignancy. The total number of patients referred for TURB increased by 47% (from 70 to 103) when using Hexvix/Cysview; however, we consider this increase in procedures justified considering that 42% of the new referrals had disease that would have otherwise been missed.

We believe that these data are supportive of approval for the US surveillance market. In addition, the safety data on repeated use of Hexvix/Cysview, as well as significantly improved detection of CIS obtained in the current study, should expand the current label to include improved detection of CIS and remove the current label restrictions on repeated use.

**Exhibit 3: Blue light cystoscopy with Hexvix/Cysview increases bladder cancer detection**



Source: Photocure

Expansion into the surveillance market is essential to the continued growth of Hexvix/Cysview, particularly in the US. The product is currently approved in the US and Europe for TURB, of which there are approximately 250,000 and 300,000 respective procedures annually. However, surveillance procedures are far more common than TURB, with approximately 1.2m procedures in the US and 750,000 in Europe per year.

## Valuation

We have adjusted our valuation to NOK947m or NOK44 per basic share, from NOK943m or NOK44 per basic share, mainly due to rolling over our NPV model to Q117. We expect approval for the US surveillance market and profitability in 2018. We may adjust our valuation in the future to reflect the initial sales trajectory of the product, as well as changes to spending associated with new marketing.

**Exhibit 4: Valuation of Photocure**

Product	Main indication	Status	Probability of commercialisation	Launch year	Peak sales (NOKm)	Patent protection	Economics	rNPV (NOKm)
Hexvix/Cysview	Bladder cancer detection	Market	100%	Launched	344	2019-20	Fully owned – US and Nordics; partner with Ipsen in EU (35% royalty)	537
Cevira	HPV-related diseases	Phase III	20%	2020	2,399	2030	17.5%	136
Visonac	Acne	Phase III	20%	2020	2,175	2028	17.5%	118
Total								792
Cash and cash equivalents (Q117)								155
<b>Total firm value</b>								<b>947</b>
Total basic shares (m)								21.6
<b>Value per basic share (NOK)</b>								<b>44</b>
Options (Q117, m)								0.1
Total number of shares (m)								21.6
Diluted value per share (NOK)								44

Source: Edison Investment Research

## Financials

We are maintaining our estimates for the most part though we have increased our 2017 sales estimate by NOK1.5m and increased our 2017 and 2018 R&D expense estimates by NOK2.3m and NOK2.4m, respectively. We continue to expect that the company will become profitable in 2018, although we expect cash flows to be negative until 2019. The company ended Q117 with NOK155m in cash, and we do not expect it to require further financing.

**Exhibit 5: Financial summary**

	NOK'000s	2015	2016	2017e	2018e
Year end 31 December		IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>					
Revenue		134,717	143,627	145,499	242,457
Cost of Sales		(8,221)	(9,337)	(11,572)	(16,947)
Gross Profit		126,496	134,291	133,927	225,510
Sales, General and Administrative Expenses		(115,025)	(124,647)	(155,241)	(194,052)
Research and Development Expense		(29,558)	(17,652)	(20,800)	(21,632)
EBITDA		(18,087)	(8,008)	(42,114)	9,827
Operating Profit (before amort. and except)		(21,986)	(15,861)	(53,660)	827
Intangible Amortisation		0	0	0	0
Other		0	0	0	0
Exceptionals		0	0	0	0
Operating Profit		(21,986)	(15,861)	(53,660)	827
Net Interest		4,553	28,640	4,742	4,932
Other		(9,771)	(366)	(313)	0
Profit Before Tax (norm)		(17,434)	12,779	(48,918)	5,758
Profit Before Tax (FRS 3)		(27,205)	12,414	(49,231)	5,758
Tax		0	(0)	0	0
Deferred tax		(0)	(0)	(0)	(0)
Profit After Tax (norm)		(17,434)	12,779	(48,918)	5,758
Profit After Tax (FRS 3)		(27,205)	12,413	(49,231)	5,758
Average Number of Shares Outstanding (m)		21.4	21.5	21.6	21.9
EPS - normalised (ore)		(82)	59	(226)	26
EPS - FRS 3 (ore)		(127)	58	(228)	26
Dividend per share (ore)		0.0	0.0	0.0	0.0
<b>BALANCE SHEET</b>					
Fixed Assets		76,394	74,070	73,368	71,970
Intangible Assets		50,615	26,390	23,684	22,088
Tangible Assets		2,288	1,660	1,286	1,484
Other		23,490	46,020	48,398	48,398
Current Assets		171,670	212,268	167,971	177,884
Stocks		13,800	17,955	14,436	27,990
Debtors		23,844	12,323	14,660	24,246
Cash		134,026	169,239	123,571	110,344
Other		0	12,750	15,304	15,304
Current Liabilities		(34,039)	(30,637)	(28,267)	(28,267)
Creditors		(34,039)	(30,637)	(28,267)	(28,267)
Short term borrowings		0	0	0	0
Long Term Liabilities		(3,960)	(3,758)	(3,955)	(4,351)
Long term borrowings		0	0	0	0
Other long term liabilities		(3,960)	(3,758)	(3,955)	(4,351)
Net Assets		210,064	251,943	209,118	217,236
<b>CASH FLOW</b>					
Operating Cash Flow		(21,030)	19,193	(38,207)	(5,626)
Net Interest		0	0	0	0
Tax		0	0	0	0
Capex		(14,930)	(21,715)	(8,469)	(8,650)
Acquisitions/disposals		0	33,213	0	0
Financing		0	0	0	0
Dividends		0	0	0	0
Other		2,326	2,394	1,008	1,048
Net Cash Flow		(33,634)	33,085	(45,668)	(13,227)
Opening net debt/(cash)		(165,245)	(134,026)	(169,239)	(123,571)
HP finance leases initiated		0	0	0	0
Exchange rate movements		2	0	0	0
Other		2413	2129	0	0
Closing net debt/(cash)		(134,026)	(169,239)	(123,571)	(110,344)

Source: Photocure accounts, Edison Investment Research

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