

Photocure

Financial update

Positive CMS draft rule change

Photocure announced results for Q217 with 10% growth for the Hexvix/Cysview franchise compared to Q216. The US was a major driver, up 55% to NOK10.9m, though partner sales fell by 9% to NOK15m due to lost reimbursement in France. The company also announced that the US Centers for Medicare and Medicaid Services (CMS) released a proposed rule that would create a new set of codes to cover Blue Light Cystoscopy (BLC) with Hexvix/Cysview. These new codes should help improve the penetration of the product into the US 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	39.0	N/A
12/17e	149.4	(44.9)	(2.08)	0.0	N/A	N/A
12/18e	242.5	5.0	0.23	0.0	100.0	N/A

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

Major reimbursement change in the US coming soon

The CMS has released a proposed rule, which is set to be finalised and issued in Q417 after the comment period expires in September. Once issued, it would result in significant improvement in the reimbursement for certain BLC with Hexvix/Cysview procedures in Medicare patients. As 73.4% of bladder cancer patients are over 65, according to the National Cancer Institute, this should help accelerate penetration of the product in the US.

US sales continue strong growth

Q217 sales in the US increased 55% (compared to 32% in Q117) to NOK10.9m, driven mainly by volume growth and price increases. Unit sales increased 37% and four additional units were installed over the quarter, bringing the total installed base to 93. Photocure is in the process of increasing its investments in marketing, as well as 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 as well as the coming improved reimbursement regime.

France was a problem, but Nordic sales recovered

Despite new French national guidelines (issued in Q416) that recommended the use of Hexvix, the product lost reimbursement in France in Q217, which resulted in partner sales as a whole to decline by 9% compared to last year. On the positive side, Nordic sales, which had been under pressure mainly due to issues in Denmark, have reversed, with revenues growing 10% to NOK11.7m.

Valuation: NOK949m or NOK44 per share

We have adjusted our valuation from NOK947m or NOK44 per basic share to NOK949m or NOK44 per basic share, mainly due to rolling over our NPV model to Q217, but the increase was mitigated by a lower cash balance. We expect increased sales in the US to drive the company to profitability in 2018.

Healthcare equipment & services

1 September 2017

Price **NOK23**
Market cap **NOK497m**

NOK7.90/US\$

Net cash (NOKm) at 30 June 2017 137

Shares in issue 21.6m

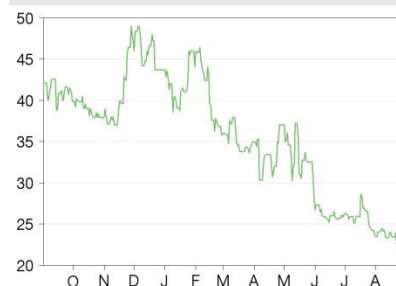
Free float 85%

Code PHO

Primary exchange Oslo

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (3.0) (18.6) (44.4)

Rel (local) (4.1) (22.2) (52.4)

52-week high/low NOK49 NOK23

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

CMS reimbursement change 1 January 2018

Surveillance market launch 2018

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Second quarter results

Photocure reported total revenue of NOK39.3m for Q217, representing 11% growth over Q116. This was driven by 10% year-on-year growth of revenues from Hexvix/Cysview (NOK37.6m vs NOK34.2m).

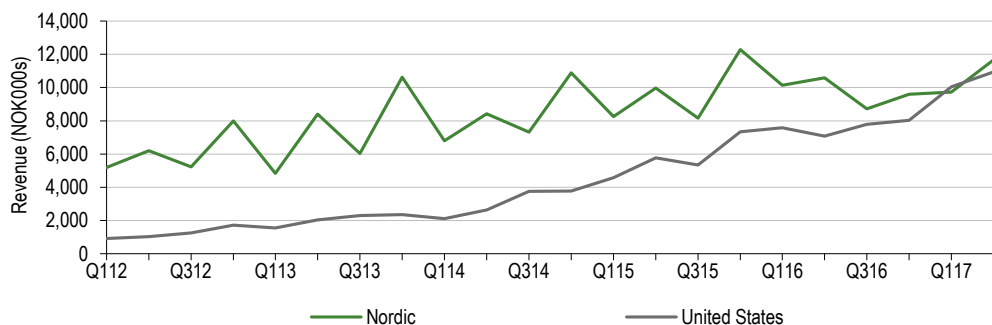
Exhibit 1: Q217 Hexvix/Cysview sales

	Revenue (NOKm)	Y-o-y	Q-o-q	Units	Y-o-y	Q-o-q
Hexvix sales Nordic	11,676	10%	20%	2,390	3%	5%
Cysview sales US	10,942	55%	9%	1,370	37%	7%
Total own sales	22,618	28%	14%	3,760	13%	6%
Partner sales	14,996	-9%	-10%	11,012	-6%	-8%
Total Hexvix/Cysview	37,614	10%	3%	14,772	-2%	-4%

Source: Photocure

Sales were especially strong in the US, where revenues grew 55% compared to Q216. End user unit sales were also strong, growing 37%, driven by an increase in the number of permanent blue light cystoscopes installed (currently 93, up from 83 at the beginning of the year) and by an increase in the usage per centre. Nordic sales finally recovered from weakness related to a reorganisation of hospitals in the Copenhagen region and were also helped by strong sales in Norway. Revenues in the Nordic region increased 10% compared to last year and a very strong 20% sequentially. These strong Q217 results have helped Nordic revenues turn positive for the year-to-date, increasing 3% compared to H116. Results in partnered areas were strongly affected by a loss of reimbursement in France so that now hospitals must bear the additional cost of the product. This move is somewhat perplexing as the new French National Guidelines for bladder cancer, which were introduced in November 2016, recommend the use of blue light cystoscopy for the first bladder resection in almost all patients. In addition, growth in the relatively new markets of Australia and Canada was hampered by the delayed placement of scopes and reimbursement issues. Year-to-date however, partner sales are only down 2% (up 1% in constant currencies) compared to H116.

Exhibit 2: Hexvix/Cysview in-market sales



Source: Photocure

SG&A for Q2 was slightly higher than recent quarters at NOK36.8m (compared to NOK33.5m in Q1). 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, lay the groundwork in preparation for the surveillance market launch and take advantage of improving reimbursement.

R&D expenses were down (to NOK4.2m from NOK8.5m), mainly due to a NOK4.0m write-down of Nedax lamp inventory (the lamp is associated with the Visonac product) in the first quarter. Also on the R&D front, the company announced that it has filed a supplemental NDA for approval of

Hexvix/Cysview in August in the surveillance setting, with approval expected in 2018. As a reminder, sales may have significant upside if the product successfully expands into the US bladder cancer surveillance market, which has 1.4m procedures per year, compared to its current market of 300,000 transurethral resection of the bladder tumour (TURBT) procedures.

US reimbursement issues resolving

Currently, Medicare does not separately reimburse centres for use of the BLC with Hexvix/Cysview procedure, but instead bundles it with the total reimbursement for TURBT procedures so any additional cost related to the product is absorbed by the centre. This has had a direct impact on the availability of BLC with Hexvix/Cysview in the US.

The issue could be potentially resolved as of 1 January 2018 thanks to a [new rule proposed by the CMS](#) that would create a new code for Blue Light Cystoscopy, which would improve reimbursement for the procedure in most situations to a level where the cost of the product would be covered. Effectively, for CPT codes 52204, 52214 and 52224, if blue light cystoscopy is used, they would qualify for reassignment to the higher ambulatory payment classification (APC) of APC 5374 from APC 5373. The company believes this will result in a \$1,000 increase in reimbursement for the CPT codes 52204, 52214 and 52224. Based on CMS procedure figures (see Exhibit 3), this would affect 54% of procedures.

Exhibit 3: CPT codes used with Hexvix/Cysview

CPT Code	Description	APC	Number of procedures (2015)	% of Total
52204	Biopsy of the bladder using an endoscope	5373	36,566	18.3%
52214	Destruction of tissue in the bladder, bladder canal (urethra) or surrounding glands using an endoscope	5373	21,950	11.0%
52224	Destruction of (less than 0.5 centimeters) growths of the bladder and bladder canal (urethra) using an endoscope	5373	49,492	24.8%
52234	Destruction and/or removal of (0.5 to 2.0 centimeters) small growths of the bladder using an endoscope	5374	31,586	15.8%
52235	Destruction and/or removal of (2.0 to 5.0 centimeters) medium growths of the bladder and bladder canal (urethra) using an endoscope	5374	36,026	18.0%
52240	Destruction and/or removal of large growths of the bladder using an endoscope	5374	24,340	12.2%
Total			199,960	100%

Source: CMS. Note: The procedure numbers only include those reimbursed by medicare and not by commercial payers.

Importantly, in the explanatory text, the CMS has admitted that blue light cystoscopy benefits patients:

“We believe that blue light cystoscopy represents an additional elective but distinguishable service as compared to white light cystoscopy that in some cases may allow greater detection of bladder tumours in beneficiaries relative to white light cystoscopy alone.”

As bladder cancer is definitely a cancer of the elderly, with 73.4% over the age of 65 at the time of diagnosis (median age is 73 years) according to the National Cancer Institute, Medicare is the key third-party payer and this is a major win for the company. We do not believe this will be a controversial rule change, so there is a high likelihood that it will be included in the final rule in Q417 (after the comment period ends in September) and implemented on 1 January 2018.

Valuation

We have adjusted our valuation from NOK947m or NOK44 per basic share to NOK949m or NOK44 per basic share, mainly due to rolling over our NPV model to Q217, but the increase was mitigated by a lower cash balance. It is important to note that we did not expect the draft CMS rule with regards to reimbursement and we may adjust our valuation in the future once we get a sense of the magnitude of the impact this rule change has on sales. Furthermore, we may adjust the valuation to

reflect the sales trajectory in the surveillance setting as well as changes to spending associated with increased 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)	550
Cevira	HPV-related diseases	Phase III	20%	2020	2,399	2030	17.5%	140
Visonac	Acne	Phase III	20%	2020	2,175	2028	17.5%	121
Total								812
Cash and cash equivalents (Q217)								137
Total firm value								949
Total basic shares (m)								21.6
Value per basic share (NOK)								44
Options (Q217, m)								0.0
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 NOK3.9m and increased both our 2017 and 2018 R&D expense estimates by NOK0.8m. We continue to expect that Photocure will become profitable in 2018, although we expect cash flows to be negative until 2019. The company ended Q217 with NOK137m 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
PROFIT & LOSS					
Revenue		134,717	143,627	149,401	242,457
Cost of Sales		(8,221)	(9,337)	(11,460)	(16,947)
Gross Profit		126,496	134,291	137,940	225,510
Sales, General and Administrative Expenses		(115,025)	(124,647)	(155,291)	(194,114)
Research and Development Expense		(29,558)	(17,652)	(21,568)	(22,430)
EBITDA		(18,087)	(8,008)	(38,918)	8,966
Operating Profit (before amort. and except)		(21,986)	(15,861)	(49,669)	(34)
Intangible Amortisation		0	0	0	0
Other		0	0	0	0
Exceptionals		0	0	0	0
Operating Profit		(21,986)	(15,861)	(49,669)	(34)
Net Interest		4,553	28,640	4,805	4,997
Other		(9,771)	(366)	(111)	0
Profit Before Tax (norm)		(17,434)	12,779	(44,864)	4,963
Profit Before Tax (FRS 3)		(27,205)	12,414	(44,975)	4,963
Tax		0	(0)	0	0
Deferred tax		(0)	(0)	(0)	(0)
Profit After Tax (norm)		(17,434)	12,779	(44,864)	4,963
Profit After Tax (FRS 3)		(27,205)	12,413	(44,975)	4,963
Average Number of Shares Outstanding (m)		21.4	21.5	21.6	21.8
EPS - normalised (ore)		(82)	59	(208)	23
EPS - FRS 3 (ore)		(127)	58	(208)	23
Dividend per share (ore)		0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets		76,394	74,070	76,689	76,297
Intangible Assets		50,615	26,390	25,024	24,811
Tangible Assets		2,288	1,660	2,383	2,204
Other		23,490	46,020	49,282	49,282
Current Assets		171,670	212,268	164,313	170,599
Stocks		13,800	17,955	15,585	27,990
Debtors		23,844	12,323	23,772	24,246
Cash		134,026	169,239	110,281	103,689
Other		0	12,750	14,675	14,675
Current Liabilities		(34,039)	(30,637)	(24,762)	(24,762)
Creditors		(34,039)	(30,637)	(24,762)	(24,762)
Short term borrowings		0	0	0	0
Long Term Liabilities		(3,960)	(3,758)	(4,234)	(4,658)
Long term borrowings		0	0	0	0
Other long term liabilities		(3,960)	(3,758)	(4,234)	(4,658)
Net Assets		210,064	251,943	212,005	217,477
CASH FLOW					
Operating Cash Flow		(21,030)	19,193	(50,453)	2,016
Net Interest		0	0	0	0
Tax		0	0	0	0
Capex		(14,930)	(21,715)	(10,073)	(10,239)
Acquisitions/disposals		0	33,213	0	0
Financing		0	0	0	0
Dividends		0	0	0	0
Other		2,326	2,394	1,568	1,631
Net Cash Flow		(33,634)	33,085	(58,958)	(6,593)
Opening net debt/(cash)		(165,245)	(134,026)	(169,239)	(110,281)
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)	(110,281)	(103,689)

Source: Company accounts, Edison Investment Research

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