

Photocure

Financial results

Q4 results and a new indication

Photocure announced results for Q417 with 25% growth for the Hexvix/Cysview franchise compared to Q416. For the year, Hexvix/Cysview revenues grew by 14% with the US being a major driver, up 39% for the year. Additionally, the company recently received approval by the FDA for Hexvix/Cysview in the surveillance setting which greatly expands the addressable market. There are 1.4m surveillance-related procedures per year, compared to 300,000 transurethral resection of bladder tumor (TURBT) procedures, where the company has historically been focused.

Year end	Revenue (NOKm)	PBT* (NOKm)	EPS* (NOK)	DPS (NOK)	P/E (x)	Yield (%)
12/16	143.6	12.8	1.64	0.0	17.6	N/A
12/17	150.9	(41.6)	(1.61)	0.0	N/A	N/A
12/18e	200.9	(28.6)	(0.96)	0.0	N/A	N/A
12/19e	288.8	44.8	1.49	0.0	19.3	N/A

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

FDA approval in surveillance setting

In mid-February, the FDA approved an expanded indication for Cysview, which includes the surveillance setting. Hexvix/Cysview 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 TURBT procedures. The company plans to launch in this setting in mid-2018.

Continued strong US growth

FY17 sales in the US increased 39% (compared to 32% in FY16) to NOK42.4m, driven mainly by volume growth and price increases. Unit sales increased 31% and 21 additional units were installed over the course of 2017 (eight of which were installed in Q417) bringing the total installed base to 104.

Increased US sales effort

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 approval in the surveillance setting as well as the improved reimbursement regime. The focus is on 400 major hospitals in the top 25 TURBT markets, which represent 40% of procedures.

Valuation: NOK898m or NOK42 per share

We have adjusted our valuation from NOK908m or NOK42 per basic share to NOK898m or NOK42 per basic share, mainly due to a more conservative view of 2018 revenue growth as it will likely take a couple of quarters for the company to see the impact of the surveillance approval (however, long term estimates remain the same). This is partly mitigated by a higher cash balance and rolling forward our NPV model to Q417. With NOK129m in cash, Photocure should have enough capital to meet its needs.

Pharma & biotech

13 March 2018

Price **NOK28.80**
Market cap **NOK622m**

NOK7.89/US\$

Net cash (NOKm) at 31 December 2017 129

Shares in issue 21.6m

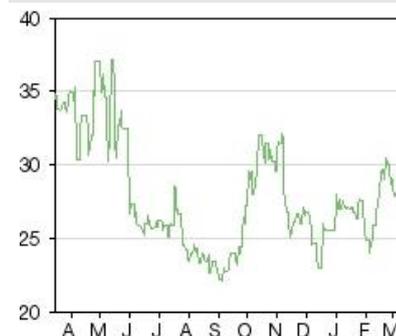
Free float 76.9%

Code PHO

Primary exchange Oslo

Secondary exchange N/A

Share price performance



%	1m	3m	12m
Abs	6.7	21.5	(24.0)
Rel (local)	4.3	19.4	(33.2)

52-week high/low NOK37.2 NOK22.1

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 launch mid-2018

Analysts

Maxim Jacobs +1 646 653 7027

Nathaniel Calloway +1 646 653 7036

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

**Photocure is a research client
of Edison Investment
Research Limited**

Q417 results

Photocure reported Hexvix/Cysview revenue of NOK39.4m for Q417, representing 25% growth over Q416. For the year, Hexvix/Cysview revenues grew by 14%.

Exhibit 1: Q417 Hexvix/Cysview sales						
	Revenue (NOKm)	Y-o-y	Q-o-q	Units	Y-o-y	Q-o-q
Hexvix sales Nordic	12,903	35%	44%	2,787	14%	33%
Cysview sales US	10,167	27%	-10%	1,265	21%	-16%
Total own sales	23,069	31%	14%	4,052	16%	13%
Partner sales	16,339	17%	7%	9,815	-9%	-3%
Total Hexvix/Cysview	39,409	25%	11%	13,867	-3%	1%

Source: Photocure

Sales in the US continued to be strong, up 27% compared to Q416. For the year, US revenues were up 39%, an acceleration compared to the 32% growth seen in FY16. End user unit sales were also strong, growing 21% for the quarter and 31% over the course of the year, driven by an increase in the number of permanent blue light cystoscopes installed (currently 104, up from 83 at the beginning of 2017).

Revenues in the Nordic region increased 35% for the quarter compared to Q416 as the region recovered from weakness a year ago and due to a build-up in inventory (which may be worked off in subsequent quarters). For the year, Nordic revenues were up 11%. Results in partnered areas increased 17% in the quarter though this was partly due to inventory build. For the year, partner revenue increased only 3% mainly due to weak sales in France (due to a loss of reimbursement) and Austria. In addition, growth in the relatively new markets of Australia and Canada was hampered by the delayed placement of scopes and reimbursement issues.

SG&A for Q4 was higher than recent quarters at NOK41.3m (compared to NOK37.6m in Q3). For the year, SG&A increased by 19.6% to NOK149.1m. SG&A will likely increase in FY18 due in large part to an increase in the number of salespeople in the US and the surveillance market launch.

R&D expenses were up to NOK5.6m from NOK4.7m in Q317. For the year, R&D increased by 29.7% to NOK22.9m as the company had increased spending for regulatory work and for the maintenance and expansion of intellectual property.

Surveillance market approval

In mid-February, the company announced that the FDA had approved Hexvix/Cysview for use in the surveillance setting. Additionally, the current label has been expanded to include improved detection of carcinoma in situ (CIS) and all restrictions on repeated use have been removed. Expansion into the surveillance market is essential to the continued growth of Hexvix/Cysview, particularly in the US. The US bladder cancer surveillance market has 1.4m procedures per year, much larger than the currently approved market for Hexvix/Cysview, 300,000 TURBT procedures.

The approval is due to clinical results presented 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). 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 endpoint 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 (BLC).

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 TURBT 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.

Exhibit 2: Blue light cystoscopy with Hexvix/Cysview increases bladder cancer detection



Source: Photocure

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 TURBT who turned out to not have a malignancy. The total number of patients referred for TURBT 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.

Valuation

We have adjusted our valuation from NOK908m or NOK42 per basic share to NOK898m or NOK42 per basic share, mainly due to a more conservative view of 2018 revenue growth as it will likely take a couple of quarters for the company to see the impact of the surveillance approval (however, long-term estimates remain the same). This is partly mitigated by a higher cash balance and rolling forward our NPV model to Q417. We may adjust the valuation further once the company provides an update on the sales trajectory in the surveillance setting as well as changes to spending associated with increased marketing.

Exhibit 3: 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)	542
Cevira	HPV-related diseases	Phase III	20%	2021	2,218	2030	17.5%	121
Visonac	Acne	Phase III	20%	2021	2,091	2028	17.5%	106
Total								769
Cash and cash equivalents (Q417)								129
Total firm value								898
Total basic shares (m)								21.6
Value per basic share (NOK)								42
Options (Q317, m)								0.0
Total number of shares (m)								21.6
Diluted value per share (NOK)								42

Source: Edison Investment Research

Financials

We have lowered our 2018 revenue estimates from NOK242.5m to NOK200.9m mainly due to a more conservative view of 2018 growth, though it remains at 33% year-on-year, an acceleration of the current growth rate. We have also introduced our 2019 estimates, which are dependent upon continued strong growth in the US market. We had previously expected Photocure to become profitable in FY18, although with negative cash flows until FY19. We now expect both events to occur in FY19. The company ended Q417 with NOK129m in cash, and we do not expect it to require further financing.

Exhibit 4: Financial summary

	NOK'000s	2015	2016	2017	2018e	2019e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue		134,717	143,627	150,911	200,873	288,758
Cost of Sales		(8,221)	(9,337)	(12,011)	(14,036)	(20,266)
Gross Profit		126,496	134,291	138,900	186,837	268,493
Sales, General and Administrative Expenses		(115,025)	(124,647)	(149,098)	(186,373)	(193,828)
Research and Development Expense		(29,558)	(17,652)	(22,896)	(23,812)	(24,764)
EBITDA		(18,087)	(8,008)	(33,094)	(23,348)	49,901
Operating Profit (before amort. and except)		(21,986)	(15,861)	(45,202)	(32,348)	40,901
Intangible Amortisation		0	0	0	0	0
Other		0	0	0	0	0
Exceptionals		0	0	0	0	0
Operating Profit		(21,986)	(15,861)	(45,202)	(32,348)	40,901
Net Interest		4,553	28,640	3,622	3,767	3,918
Other		(9,771)	0	0	0	0
Profit Before Tax (norm)		(17,434)	12,779	(41,580)	(28,581)	44,819
Profit Before Tax (FRS 3)		(27,205)	12,779	(41,580)	(28,581)	44,819
Tax		(8,108)	22,530	6,883	7,717	(12,101)
Deferred tax		(0)	(0)	(0)	(0)	(0)
Profit After Tax (norm)		(25,541)	35,309	(34,697)	(20,864)	32,718
Profit After Tax (FRS 3)		(35,312)	35,309	(34,697)	(20,864)	32,718
Average Number of Shares Outstanding (m)		21.4	21.5	21.6	21.8	22.0
EPS - normalised (ore)		(120)	164	(161)	(96)	149
EPS - FRS 3 (ore)		(165)	164	(161)	(96)	149
Dividend per share (ore)		0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets		76,394	74,070	87,486	87,176	86,814
Intangible Assets		50,615	26,390	33,315	32,093	30,774
Tangible Assets		2,288	1,660	1,268	2,180	3,136
Other		23,490	46,020	52,903	52,903	52,903
Current Assets		171,670	212,268	175,613	156,930	191,984
Stocks		13,800	17,955	19,552	23,189	33,335
Debtors		23,844	12,323	14,573	20,087	28,876
Cash		134,026	169,239	129,368	101,534	117,653
Other		0	12,750	12,119	12,119	12,119
Current Liabilities		(34,039)	(30,637)	(40,267)	(40,267)	(40,267)
Creditors		(34,039)	(30,637)	(40,267)	(40,267)	(40,267)
Short term borrowings		0	0	0	0	0
Long Term Liabilities		(3,960)	(3,758)	(4,752)	(5,228)	(5,750)
Long term borrowings		0	0	0	0	0
Other long term liabilities		(3,960)	(3,758)	(4,752)	(5,228)	(5,750)
Net Assets		210,064	251,943	218,079	198,611	232,780
CASH FLOW						
Operating Cash Flow		(21,030)	19,193	(23,593)	(19,144)	24,757
Net Interest		0	0	0	0	0
Tax		0	0	0	0	0
Capex		(14,930)	(21,715)	(18,588)	(11,092)	(11,136)
Acquisitions/disposals		0	33,213	0	0	0
Financing		0	0	0	0	0
Dividends		0	0	0	0	0
Other		2,326	2,394	2,310	2,402	2,498
Net Cash Flow		(33,634)	33,085	(39,871)	(27,834)	16,120
Opening net debt/(cash)		(165,245)	(134,026)	(169,239)	(129,368)	(101,534)
HP finance leases initiated		0	0	0	0	0
Exchange rate movements		2	0	0	0	0
Other		2413	2129	0	0	0
Closing net debt/(cash)		(134,026)	(169,239)	(129,368)	(101,533)	(117,653)

Source: Company accounts, Edison Investment Research

Edison is an investment research and advisory company, with offices in North America, Europe, the Middle East and AsiaPac. The heart of Edison is our world-renowned equity research platform and deep multi-sector expertise. At Edison Investment Research, our research is widely read by international investors, advisers and stakeholders. Edison Advisors leverages our core research platform to provide differentiated services including investor relations and strategic consulting. Edison is authorised and regulated by the [Financial Conduct Authority](#). Edison Investment Research (NZ) Limited (Edison NZ) is the New Zealand subsidiary of Edison. Edison NZ is registered on the New Zealand Financial Service Providers Register (FSP number 247505) and is registered to provide wholesale and/or generic financial adviser services only. Edison Investment Research Inc (Edison US) is the US subsidiary of Edison and is regulated by the Securities and Exchange Commission. Edison Investment Research Pty Limited (Edison Aus) [46085869] is the Australian subsidiary of Edison. Edison Germany is a branch entity of Edison Investment Research Limited [4794244]. www.edisongroup.com

DISCLAIMER

Copyright 2018 Edison Investment Research Limited. All rights reserved. This report has been commissioned by Photocure and prepared and issued by Edison for publication globally. All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report. Opinions contained in this report represent those of the research department of Edison at the time of publication. The securities described in the Investment Research may not be eligible for sale in all jurisdictions or to certain categories of investors. This research is issued in Australia by Edison Investment Research Pty Ltd (Corporate Authorised Representative (1252501) of Myonlineadvisers Pty Ltd (AFSL: 427484)) and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. The Investment Research is distributed in the United States by Edison US to major US institutional investors only. Edison US is registered as an investment adviser with the Securities and Exchange Commission. Edison US relies upon the "publishers' exclusion" from the definition of investment adviser under Section 202(a)(11) of the Investment Advisers Act of 1940 and corresponding state securities laws. As such, Edison does not offer or provide personalised advice. We publish information about companies in which we believe our readers may be interested and this information reflects our sincere opinions. The information that we provide or that is derived from our website is not intended to be, and should not be construed in any manner whatsoever as, personalised advice. Also, our website and the information provided by us should not be construed by any subscriber or prospective subscriber as Edison's solicitation to effect, or attempt to effect, any transaction in a security. The research in this document is intended for New Zealand resident professional financial advisers or brokers (for use in their roles as financial advisers or brokers) and habitual investors who are "wholesale clients" for the purpose of the Financial Advisers Act 2008 (FAA) (as described in sections 5(c) (1)(a), (b) and (c) of the FAA). This is not a solicitation or inducement to buy, sell, subscribe, or underwrite any securities mentioned or in the topic of this document. This document is provided for information purposes only and should not be construed as an offer or solicitation for investment in any securities mentioned or in the topic of this document. A marketing communication under FCA Rules, this document has not been prepared in accordance with the legal requirements designed to promote the independence of investment research and is not subject to any prohibition on dealing ahead of the dissemination of investment research. Edison has a restrictive policy relating to personal dealing. Edison Group does not conduct any investment business and, accordingly, does not itself hold any positions in the securities mentioned in this report. However, the respective directors, officers, employees and contractors of Edison may have a position in any or related securities mentioned in this report. Edison or its affiliates may perform services or solicit business from any of the companies mentioned in this report. The value of securities mentioned in this report can fall as well as rise and are subject to large and sudden swings. In addition it may be difficult or not possible to buy, sell or obtain accurate information about the value of securities mentioned in this report. Past performance is not necessarily a guide to future performance. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results, estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations. For the purpose of the FAA, the content of this report is of a general nature, is intended as a source of general information only and is not intended to constitute a recommendation or opinion in relation to acquiring or disposing (including refraining from acquiring or disposing) of securities. The distribution of this document is not a "personalised service" and, to the extent that it contains any financial advice, is intended only as a "class service" provided by Edison within the meaning of the FAA (ie without taking into account the particular financial situation or goals of any person). As such, it should not be relied upon in making an investment decision. To the maximum extent permitted by law, Edison, its affiliates and contractors, and their respective directors, officers and employees will not be liable for any loss or damage arising as a result of reliance being placed on any of the information contained in this report and do not guarantee the returns on investments in the products discussed in this publication. FTSE International Limited ("FTSE") © FTSE 2018. "FTSE®" is a trade mark of the London Stock Exchange Group companies and is used by FTSE International Limited under license. All rights in the FTSE indices and/or FTSE ratings vest in FTSE and/or its licensors. Neither FTSE nor its licensors accept any liability for any errors or omissions in the FTSE indices and/or FTSE ratings or underlying data. No further distribution of FTSE Data is permitted without FTSE's express written consent.