EDISON

Photocure

Clinical results

Phase III surveillance trial successful

Pharma & biotech

Photocure presented the findings of from its Phase III clinical trial of Hexvix/Cysview for bladder cancer surveillance at the American Urological Association annual meeting. These results showed that the product increased the detection of patients with recurrence by 21.5% (p<0.0001). In particular, detection of carcinoma in situ was improved by 34.6% (p<0.0001). We believe these data are supportive of marketing authorisation for the bladder cancer surveillance 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	N/A	N/A
12/17e	144.0	(42.9)	(1.98)	0.0	N/A	N/A
12/18e	242.5	9.1	0.42	0.0	N/A	N/A

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

Hexvix/Cysview catches more recurrences

The clinical trial enrolled 304 patients with non-muscle invasive bladder cancer that were considered a high risk of recurrence and underwent both white light and blue light cystoscopy with Hexvix/Cysview. Of these, 220 were in the experimental portion of the trial and evaluable for efficacy. 33 more referrals for resection (of 103 total) were made on the basis of blue light cystoscopy and 14 more patients with recurrence were identified (of 65 total) that would have otherwise been missed.

…and more tumours total

Blue light cystoscopy with Hexvix/Cysview improved cancer detection by all metrics. The 34.6% improvement in the detection of carcinoma in situ is significant because these lesions are flat and difficult to identify using white light, but frequently develop into malignant masses. Additionally, 46.2% of patients with cancer had more lesions identified with the addition of blue light cystoscopy, which we expect to translate into better long-term outcomes.

Surveillance market at over 1.2m in US

Hexvix/Cysview is currently approved for transurethral resection of the bladder (TURB) of which there are approximately 250,000 procedures in the US and 300,000 in Europe per year. After resection, however, patients are recommended to undergo frequent surveillance: every three months for the first three years and yearly thereafter. There are 1.2m surveillance cystoscopies in the US and 750,000 in Europe per year, presenting a significant growth opportunity.

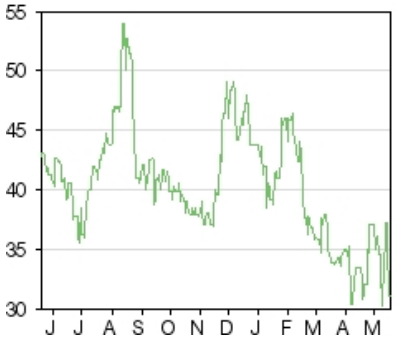
Valuation: Increased to NOK943m or NOK44

We have increased our valuation to NOK943m or NOK44 per basic share from NOK886m or NOK41 per basic share due to an increase in our peak sales estimates for Hexvix/Cysview to NOK344m from NOK324m. We expect approval for the US surveillance market and profitability in 2018. The company ended Q416 with NOK169m in cash, and we do not expect it to require further financing.

18 May 2017

Price	**NOK31.00**
Market cap	**NOK668m**
	NOK8.47/US$
Net cash (NOKm) at 31 December 2016	169
Shares in issue	21.6m
Free float	84.98%
Code	PHO
Primary exchange	Oslo
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(7.2)	(17.6)	(27.6)
Rel (local)	(9.7)	(23.4)	(38.4)
52-week high/low	NOK54.0		NOK27.5

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 event

Surveillance market launch	2018

Analysts

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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 transurethral resection of the bladder (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 American Urological Association recommends surveillance every three to six months for the first three years after diagnosis and yearly thereafter.

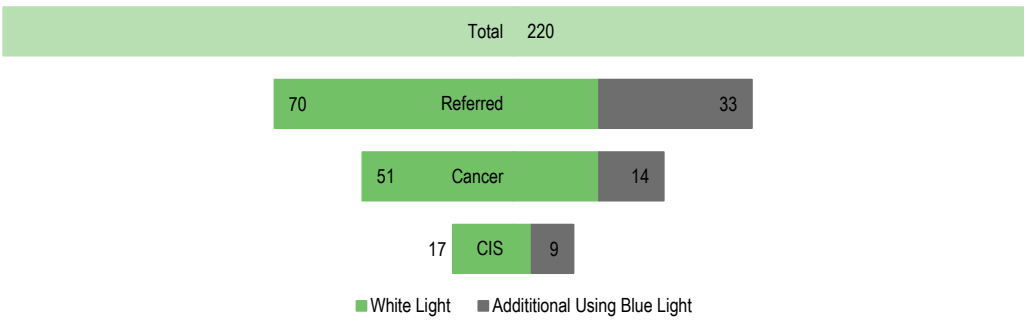
The clinical trial enrolled 304 patients at 17 institutions in the US. It only enrolled patients with a high probability of recurrence as identified by having multiple tumours, a previous recurrence, and/or high grade tumours in previous procedures. Patients on the study underwent both blue light and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

Exhibit 1: 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 Transurethral resection of the bladder (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 increased our valuation to NOK943m or NOK44 per basic share from NOK886m or NOK41 per basic share due to an increase in our peak sales estimates for Hexvix/Cysview. We have a higher degree of confidence in the performance of the product in the US market on the basis of the surveillance clinical trial data, and we have increased our peak sales estimates for the product to NOK344m from NOK324m. We currently forecast US approval for the surveillance market in 2018. We may adjust our valuation in the future to reflect the initial sale trajectory of the product as well as changes to spending associated with new marketing.

Exhibit 2: 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)	525
Cevira	HPV-related diseases	Phase III	20%	2020	2,399	2030	17.5%	133
Visonac	Acne	Phase III	20%	2020	2,175	2028	17.5%	115
Total								773
Cash and cash equivalents (Q416)								169
Total firm value								943
Total basic shares (m)								21.6
Value per basic share (NOK)								44
Options (Q416, m)								0.1
Total number of shares (m)								21.7
Diluted value per share (NOK)								43

Source: Photocure reports, Edison Investment Research

Financials

Our new financials reflect our adjustment to the new sales trajectory for Hexvix/Cysview in the US. We have increased our 2018 sales estimate to NOK242m from NOK231m, and carry this increase forward. We now expect that the company will become profitable in 2018 (compared to previous forecasts of 2019), although we expect cash flows to be negative until 2019. The company ended 2016 with NOK169m in cash, and we do not expect it to require additional capital.

Exhibit 3: Financial summary

NOK'000s	2015	2016	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	134,717	143,627	143,977	242,457
Cost of Sales	(8,221)	(9,337)	(9,961)	(16,947)
Gross Profit	126,496	134,291	134,015	225,510
Sales, General and Administrative Expenses	(115,025)	(124,647)	(155,808)	(194,760)
Research and Development Expense	(29,558)	(17,652)	(18,534)	(19,276)
EBITDA	(18,087)	(8,008)	(40,327)	11,474
Operating Profit (before amort. and except)	(21,986)	(15,861)	(48,180)	3,621
Intangible Amortisation	0	0	0	0
Other	0	0	0	0
Exceptionals	0	0	0	0
Operating Profit	(21,986)	(15,861)	(48,180)	3,621
Net Interest	4,553	28,640	5,272	5,483
Other	(9,771)	(366)	0	0
Profit Before Tax (norm)	(17,434)	12,779	(42,908)	9,104
Profit Before Tax (FRS 3)	(27,205)	12,414	(42,908)	9,104
Tax	0	(0)	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(17,434)	12,779	(42,908)	9,104
Profit After Tax (FRS 3)	(27,205)	12,413	(42,908)	9,104
Average Number of Shares Outstanding (m)	21.4	21.5	21.7	21.9
EPS - normalised (ore)	(82)	59	(198)	42
EPS - FRS 3 (ore)	(127)	58	(198)	42
Dividend per share (NOK)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	76,394	74,070	96,127	89,875
Intangible Assets	50,615	26,390	48,706	42,584
Tangible Assets	2,288	1,660	1,401	1,272
Other	23,490	46,020	46,020	46,020
Current Assets	171,670	212,268	162,945	180,086
Stocks	13,800	17,955	16,621	27,990
Debtors	23,844	12,323	22,167	37,329
Cash	134,026	169,239	111,407	102,017
Other	0	12,750	12,750	12,750
Current Liabilities	(34,039)	(30,637)	(30,637)	(30,637)
Creditors	(34,039)	(30,637)	(30,637)	(30,637)
Short term borrowings	0	0	0	0
Long Term Liabilities	(3,960)	(3,758)	(4,134)	(4,547)
Long term borrowings	0	0	0	0
Other long term liabilities	(3,960)	(3,758)	(4,134)	(4,547)
Net Assets	210,064	251,943	224,301	234,777
CASH FLOW				
Operating Cash Flow	(21,030)	19,193	(28,707)	(8,575)
Net Interest	0	0	0	0
Tax	0	0	0	0
Capex	(14,930)	(21,715)	(31,614)	(3,405)
Acquisitions/disposals	0	33,213	0	0
Financing	0	0	0	0
Dividends	0	0	0	0
Other	2,326	2,394	2,490	2,589
Net Cash Flow	(33,634)	33,085	(57,832)	(9,390)
Opening net debt/(cash)	(165,245)	(134,026)	(169,239)	(111,407)
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)	(111,407)	(102,017)

Source: Photocure reports, Edison Investment Research

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