EDISON

Photocure

Development update

Looking at other strategic opportunities

Pharma & biotech

Photocure recently announced that after seeking partners for Cevira and Visonac for the last few years, it is expanding the search to include outright sale of those products, possible spinoffs or other strategic alternatives. While partnership discussions are continuing, the chances that these will be successful appear diminished. As such, we have removed all partnership related milestones from our model and reduced the probability of success for Cevira from 50% to 20% and for Visonac from 60% to 20% as it is unclear how successful the broadened strategic search will be.

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	230.6	(1.9)	(0.09)	0.0	N/A	N/A

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

Development risk and commercial concerns

Photocure has indicated that feedback it has received during partnership discussions expressed concerns with regards to development risk with Cevira (key data based on 40 patients out of a 262-patient Phase IIb trial) and the current combination of drug and device for Visonac.

Spinoff appears more likely than outright sale

It appears unlikely that if potential partners were unwilling to pay to own less than 100% of Cevira and Visonac they would want to pay to own 100%, though this might be possible in certain cases as criteria may differ. A spinoff in which a subsidiary is capitalised and then shares sold to outside investors appears the likely scenario for both products.

New board members bring broad, deep experience

On 27 April, Photocure will host its annual meeting in Oslo. It is expected to elect three new board members, including a new chairman. All three have significant operational, consulting and business development experience within the healthcare industry.

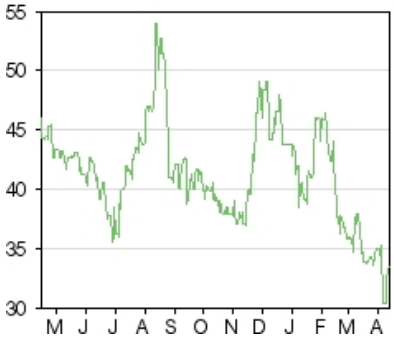
Valuation: NOK886m or NOK41 per share

We have decreased our valuation from NOK1,511m or NOK70 per share to NOK886m or NOK41 per share. This is due to the removal of all Visonac and Cevira partnership-related milestones from our model and setting their probabilities of success to 20%. This has reduced our rNPV for Cevira by 67.5% and for Visonac by 75.3%. Together, these two products are now valued at NOK248m ($28.8m). We will review our valuations for these products upon any updates on the new, broader strategic option process. The bulk of our current valuation is now made up of the currently marketed Hexvix/Cysview franchise (NOK469m or NOK22 per share).

13 April 2017

Price	**NOK33.40**
Market cap	**NOK720m**
	NOK8.62/US$
Net cash (NOKm) as at 31 December 2016	169
Shares in issue	21.6m
Free float	89%
Code	PHO
Primary exchange	Oslo
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(11.9)	(16.5)	(20.5)
Rel (local)	(11.3)	(16.0)	(32.0)
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 events

Surveillance trial results	Mid-2017

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Edison profile page

Partnership unlikely for Cevira and Visonac

Photocure recently announced that after seeking partners for Cevira and Visonac for the last few years, it is expanding the search to include outright sale of those products, possible spinoffs or other strategic alternatives. While partnership discussions are continuing, the chances that these will be successful appear diminished (a risk that we had highlighted previously). Feedback indicates that there are concerns with regards to development risk with Cevira and the current combination of drug and device for Visonac.

Clinical data risk for Cevira

As a reminder, Cevira is a non-invasive photodynamic therapy based on a gel form of hexylaminolevulinate (HAL) under development for HPV-related (cervical) diseases and has an SPA in place with the FDA. It consists of an HAL gel along with a disposable battery-powered LED device that is inserted next to the cervix. The HAL gel surrounds the cervix and after five hours, the time it takes for the gel to enter infected cells and be metabolised, the device's LEDs are activated for 4.5 hours. The LEDs then activate the drug and kill the abnormal, precancerous cells (although some normal cells are also killed).

The company ran a 262-patient Phase IIb trial comparing three different concentrations of HAL gel (0.2%, 1% and 5%) to placebo. The primary endpoint was lesion response rate at three months, with a response originally defined as histological regression to CIN1 or normal, cytology of LSIL or less severe and HPV negative. The 0.2% and 1% doses were no different from placebo, although the 5% dose showed a 73% response in confirmed CIN1/2 patients vs 60% placebo (p=0.2). However, there was a statistically significant response in the HAL 5% dose patients with confirmed CIN2. 18 of 19 (95%) patients in the HAL arm compared to 12 of 21 (57%) patients in placebo responded (p<0.001). Importantly, among patients with the oncogenic HPV 16/18 subtypes, which are responsible for 70%[1] of cervical cancer cases, HPV clearance was seen in five of six (83%) patients in the HAL arm compared to two of six (33%) in placebo at the six-month point.

Also, at the behest of the FDA, the company conducted a reanalysis of the results, which included a new pathological assessment conducted by a panel of three independent pathologists (originally the samples were only read by one pathologist) and applied new clinical success criteria. As a result of this re-read of the results, 76% of HSIL patients in the Cevira group responded compared to 28% in the treatment arm, a statistically significant difference.

Of course, a major caveat here (and potentially a key reason why potential partners are hesitant) is that the previous data are from small numbers of patients. Out of a 262-patient trial, these data come from less than 20% of the total intent-to-treat trial population. Whoever takes over Cevira would either need to run another Phase II to better understand the risk-reward of a Phase III trial or simply stomach the risk with the understanding that they are moving forward with limited data.

Commercial risk for Visonac

Visonac is a photodynamic therapy for moderate to severe inflammatory acne. It is a cream that contains methyl aminolevulinate (MAL) as its active ingredient, which is the same active ingredient as that of Metvix, Photocure's first approved product for skin cancers, which was divested to Galderma in 2009 for €51m. It works by killing the bacteria *P. acnes* and decreasing sebum (oil) production.

1 Bosch et al., International Journal of Gynecology and Obstetrics (2006) 94 (Supplement 1), S8-S21.

Visonac therapy consists of applying the cream to the face and allowing it to be absorbed by the skin and bacteria in the pustules for 90 minutes. The cream is then washed off and the face is exposed to red light for 10 minutes. This process is then repeated an additional three times over the next six weeks. In a 153-patient Phase IIb trial, Visonac demonstrated efficacy that was comparable to and possibly slightly better than Solodyn (see Exhibit 1), which in 2011 had sales of $761m in the US. There were no serious adverse events, but 12% of those in the treatment arm (compared to 0% in the placebo arm) dropped out of the trial due to adverse events, mainly burning/pain during illumination, which was an issue seen with Metvix and other MAL studies over the years.

Exhibit 1: Visonac vs Solodyn

Drug	Treatment arm: % change in inflammatory lesion counts from baseline at week 12	Placebo arm: % change in inflammatory lesion counts from baseline at week 12	Placebo-adjusted % change in lesion counts	p-value	Drop-out rate due to adverse events (%)
Solodyn (Study 04, n=451)	43.1	31.7	11.4	p=0.001	3.0
Solodyn (Study 05, n=473)	45.8	30.8	15.0	p<0.001	2.5
Visonac (Phase IIb, n=153)	43.8	26.6	17.2	p=0.003	12.0

Source: FDA, clinicaltrials.gov

The issue with potential partners is that the Phase IIb exclusively used the Nedax full-face lamp. If the Phase III used the same lamp and the product was approved on that data, that would require dermatologists to acquire another light source in order to use Visonac and many dermatologists already have multiple light sources in their office. A new partner might have to run additional Phase II trials with additional light sources in order to increase the chance of having a broader label and enabling dermatologists to use Visonac without additional capital expenditures.

New board members

At the April 27 annual meeting, three new board members are expected to be elected, including a new Chairman. Dr Jan Egberts, the nominee for chairman, has held various business development and management positions at Merck and Johnson & Johnson, leading buyouts. He has also been CEO of a specialty pharma company and a molecular diagnostics company. Currently he is a managing partner of a private equity company focused on healthcare. Dr Johanna Holldack has experience in clinical trials, drug approvals, IPOs and licensing, and has managed several mergers and acquisitions. Gwen Melincoff has held senior business development positions at BTG and Shire and led Shire's corporate venture fund. Given the experience of these prospective board members, they may assist Photocure in monetising its assets.

Valuation

We have decreased our valuation from NOK1,511m or NOK70 per share to NOK886m or NOK41 per share. This is due to the removal of all Visonac and Cevira partnership related milestones (NOK360m total for Visonac and NOK240m total for Cevira, spread over the next 8-10 years) from our model and setting their probabilities of success to 20% given the company's inability to consummate a partnership transaction. We continue to expect Photocure to retain 17.5% of the economics as it would likely retain a minority shareholding in any spinoff after outside investors capitalise the company. As mentioned above, we view the probability for an outright sale as low. These changes have reduced our rNPV for Cevira by 67.5% and for Visonac by 75.3%. Together, these two products are now valued at NOK248m ($28.8m). We will review our valuations for these products upon any updates on the new, broader strategic option process.

Exhibit 2: Photocure valuation table

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	324	2019-20	Fully owned – US and Nordics; partner with Ipsen in EU (35% royalty)	469
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								717
Cash and cash equivalents (Q416)								169
Total firm value								**886**
Total basic shares (m)								21.6
Value per basic share (NOK)								**41**
Options (Q416, m)								0.1
Total number of shares (m)								21.7
Diluted value per share (NOK)								41

Source: Photocure reports, Edison Investment Research

Financials

The Hexvix/Cysview franchise is profitable, with NOK30m in EBITDA in 2016, though the company as a whole had an EBITDA loss of NOK8m over the course of the year. The biggest upside currently to future sales of Hexvix/Cysview is expansion into the US bladder cancer surveillance market, which has 1.2m procedures per year, compared to the current market of 250,000 transurethral resection of the bladder procedures. Photocure is in a pivotal Phase III clinical trial, and it announced as of February 2017 that the trial was fully enrolled. The primary readout will be the number of malignancies that were caught using Hexvix/Cysview that were missed with normal white light cystoscopy. Top-line data are expected in mid-2017.

With NOK169.2m in cash at the end of 2016, no change to our 2017 and 2018 financial forecasts and a continued expectation for 2019 profitability, Photocure should have enough capital to attain profitability.

Exhibit 3: Financial summary

NOK000s	2015	2016	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	134,717	143,627	143,977	230,576
Cost of Sales	(8,221)	(9,337)	(9,961)	(16,115)
Gross Profit	126,496	134,291	134,015	214,461
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)	425
Operating Profit (before GW and except.)	(21,986)	(15,861)	(48,180)	(7,428)
Intangible Amortisation	0	0	0	0
Other	0	0	0	0
Exceptionals	0	0	0	0
Operating Profit	(21,986)	(15,861)	(48,180)	(7,428)
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)	(1,945)
Profit Before Tax (FRS 3)	(27,205)	12,414	(42,908)	(1,945)
Tax	0	(0)	0	0
Deferred tax	(0)	(0)	(0)	(0)
Profit After Tax (norm)	(17,434)	12,779	(42,908)	(1,945)
Profit After Tax (FRS 3)	(27,205)	12,413	(42,908)	(1,946)
Average Number of Shares Outstanding (m)	21.4	21.5	21.7	21.9
EPS - normalised (ore)	(82)	59	(198)	(9)
EPS - FRS 3 (ore)	(127)	58	(198)	(9)
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	172,020
Stocks	13,800	17,955	16,621	26,618
Debtors	23,844	12,323	22,167	35,500
Cash	134,026	169,239	111,407	97,152
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	226,711
CASH FLOW				
Operating Cash Flow	(21,030)	19,193	(28,707)	(13,440)
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)	(14,256)
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)	(97,152)

Source: Photocure reports, Edison Investment Research

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