

Photocure

Financial update

Strong revenue growth

Photocure has announced results for Q318, with 25% revenue growth compared to Q317. Revenues grew strongly in the US, where Hexvix/Cysview sales increased 46% over Q317. This was driven mainly by improved reimbursement and a higher installed base of blue light cystoscopes. Importantly, the company has received new medicare coding, which will increase reimbursement for the use of Hexvix/Cysview starting in 2019.

Year end	Revenue (NOKm)	PBT* (NOKm)	EPS* (NOK)	DPS (NOK)	P/E (x)	Yield (%)
12/16	143.6	12.8	1.64	0.0	22.9	N/A
12/17	150.9	(41.6)	(1.61)	0.0	N/A	N/A
12/18e	184.6	(21.9)	(0.73)	0.0	N/A	N/A
12/19e	251.0	35.7	1.20	0.0	31.3	N/A

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

US driving growth

Q318 sales in the US increased 46% to NOK16.5m and are up 40% over the first nine months of the year. Unit sales increased 35% during the quarter and are up 38% year-to-date. The total installed base of blue light cystoscopes (both rigid and flexible) increased to 137, up from 104 at the beginning of 2018.

Improved reimbursement

The company also announced that the US Centers for Medicare and Medicaid Services (CMS) released a final rule that would create a new code to cover blue light cystoscopy with Hexvix/Cysview when used in physician offices and other sites. CMS also continued a specific complexity adjustment for certain procedures in hospital outpatient departments. As 73.4% of bladder cancer patients are over 65 (according to the National Cancer Institute), and hence covered by Medicare, this should help accelerate penetration of the product in the US.

Partner and Nordic sales growing

Partner revenue increased 8% in the third quarter, with in-market unit sales up 6% thanks to strength in France and Germany. Nordic revenues were up 19% mainly due to price increases and favourable comparables due to a distributor inventory reduction in the third quarter of last year.

Valuation: NOK970m or NOK45 per share

We have adjusted our valuation from NOK954m or NOK44 per basic share to NOK970m or NOK45 per basic share. We lowered our near-term Hexvix/Cysview forecasts due to a lower than expected run rate but increased our longer-term forecasts as we believe the sales decline stemming from competition following patent expiration would be more limited than we previously forecast. Also, we pushed back our Cevira and Visonac launch dates to 2022 from 2021 due to the lack of a partner. With NOK93m in cash, Photocure should have enough capital to meet its needs, as we expect profitability in 2019.

Pharma & biotech

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Price **NOK37.50**
Market cap **NOK810m**

NOK8.5/US\$

Net cash (NOKm) at 30 September 2018 93

Shares in issue 21.6m

Free float 72.7%

Code PHO

Primary exchange Oslo

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (25.5) (16.2) 40.5

Rel (local) (20.8) (10.3) 36.7

52-week high/low NOK63.5 NOK23.0

Business description

Photocure specialises in photodynamic therapy. Its bladder cancer imaging product is sold as Hexvix in Europe and Cysview in the US. It 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

Update on surveillance market launch 2019

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Q318 results

Photocure reported revenue of NOK44.4m for Q318, representing 25% growth over Q317; an acceleration compared to the 16% growth seen last quarter. Hexvix/Cysview revenues were up 23%. Sales in the US continued to be strong, up 46% compared to Q317, although sequentially sales in the US were up only 3%, likely due to seasonality. End-user unit sales were also strong, growing 35% for the quarter compared to last year, driven in part by an increase in permanent blue light cystoscopes installed (currently 137, up from 104 at the beginning of the year).

Revenues in the Nordic region increased 19% to NOK10.6m after declining 8% in Q218. The increase was mainly due to price increases as well as a soft Q317 caused by a distributor inventory decline in that quarter. End-user unit sales in the region were down 1% compared to Q317. For the first three quarters of the year Nordic revenues are up 10% compared to last year, although end-user unit sales are down 3% due to large hospital deliveries in Denmark at the end of 2017.

Results in partnered areas increased 8% to NOK16.4m in the quarter and were up 5% on a sequential-quarter basis. Reported revenues were positively affected by an NOK2.1m accounting adjustment related to IFRS 15 (there was a negative impact of NOK1.2m last quarter). End-user unit sales increased 6% due to strength in the French and German markets.

SG&A for Q3 was higher sequentially at NOK40.4m (compared to NOK37.8m last quarter) although it is ramping up more slowly than we anticipated and is still lower than the previous peak of NOK41.3m, which we saw in Q4 of last year. SG&A has been affected by Photocure streamlining the organisation outside of the commercial franchise. R&D expenses remained under control at NOK2.4m as the regulatory work surrounding FDA approval for the surveillance market has now been completed.

Change in reimbursement

The company also announced that CMS has released a final rule that would create a new code to cover blue light cystoscopy with Hexvix/Cysview when used in physician offices and clinical settings of care. CMS also continued a specific blue light cystoscopy complexity adjustment payment of an additional \$1,187 for certain procedures in hospital outpatient departments. Both are effective starting 1 January 2019. The company estimates this coding will result in coverage for around 50% of the TURBT Medicare market and 100% of physician office use. As a reminder, Medicare coverage is particularly important for Photocure as bladder cancer is 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, making CMS the key third-party payer.

Exhibit 1: US reimbursement summary for Hexvix/Cysview by setting

Procedure	Medicare	Private/commercial insurance
Cystoscopy	A procedure fee for the cystoscopy with Cysview paid at average selling price + 6% in clinic or physician's office setting with new code (A9589)	A procedure fee for the cystoscopy with Cysview paid at average selling price + 6-15% (depending on contract with private payer)
TURBT	Hospital outpatient departments will receive an additional \$1,187 to cover the complexity of Cysview for codes 52204 and 52224. Reimbursement is bundled for codes 52214, 52234, 52235 and 52240 with a new add in code (A9589)	A procedure fee for the TURBT with Cysview paid at average selling price + 6-15% (depending on contract with private payer)

Source: Photocure

Valuation

We have adjusted our valuation from NOK954m or NOK44 per basic share to NOK970m or NOK45 per basic share. We lowered our near-term Hexvix/Cysview forecasts due to a lower than expected

run rate as we expected a faster ramp up following approval in the surveillance setting. However, we also increased our longer-term forecasts as further review of the regulatory and commercial environment has led us to believe the sales decline stemming from competition following patent expiration would be more limited than we previously forecast, which led to a net increase in our NPV for Hexvix/Cysview. As a reminder, patents are set to expire in September 2019 in the EU and November 2020 in the US, although any potential competitor would likely need to run some sort of clinical trial and get approval from both the Center for Devices and Radiological Health and Center for Drug Evaluation and Research due to the nature of Hexvix/Cysview as a drug/device combination. This additional cost (both clinical and regulatory) would limit the attractiveness of this market to certain competitors, especially generic competitors, as generic companies are not specialised in devices. Also, as Hexvix/Cysview is part of a procedure rather than part of a pharmaceutical benefit for patients, payers are unlikely to force conversion to the generic product and hospitals will be able to make their own decisions, based largely on price and physician preference. That said, we continue to model a sales decline starting in 2020, although this may be revised as we get additional clarity on the competitive landscape and timelines.

Additionally, we pushed back our Cevira and Visonac launch dates to 2022 from 2021 due to the lack of a partner and no clarity on the strategic review of these programmes. This resulted in lower peak sales for both these products as well as a delayed timeline due to shorter periods of patent protection once on the market. We also rolled forward our NPVs.

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	295	2019-20	Fully owned - US and Nordics, Partner with Ipsen in EU (35% royalty)	674
Cevira	HPV-related diseases	Phase III	20%	2022	2,133	2030	17.5%	110
Visonac	Acne	Phase III	20%	2022	2,011	2028	17.5%	93
Total								877
Cash and cash equivalents (Q318)								93
Total firm value								970
Total basic shares (m)								21.6
Value per basic share (NOK)								45
Options (Q318, m)								0.0
Total number of shares (m)								21.6
Diluted value per share (NOK)								45

Source: Edison Investment Research

Financials

We have decreased our 2018 revenue estimate to NOK184.6m from NOK201.5m and our 2019 revenue estimate from NOK288.8m to NOK251.0m due to a lower than expected run rate. We have also reduced our SG&A estimates for 2018 by NOK9.6m and for 2019 by NOK10.0m due to lower than expected SG&A expenses. However, we continue to expect SG&A to grow due to the company's increased investment in the US market. The company ended Q318 with NOK93m in cash, and we do not expect it to require further financing as we continue to expect profitability in 2019.

Exhibit 3: Financial summary

	NOK'000s	2016	2017	2018e	2019e
Year end 31 December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		143,627	150,911	184,568	251,003
Cost of Sales		(9,337)	(12,011)	(15,888)	(17,623)
Gross Profit		134,291	138,900	168,680	233,380
Sales, General and Administrative Expenses		(124,647)	(149,098)	(167,757)	(174,467)
Research and Development Expense		(17,652)	(22,896)	(9,754)	(10,144)
EBITDA		(8,008)	(33,094)	(8,830)	48,769
Operating Profit (before amort. and except.)		(15,861)	(45,202)	(21,917)	35,683
Intangible Amortisation		0	0	0	0
Other		0	0	0	0
Exceptionals		0	0	(13,133)	0
Operating Profit		(15,861)	(45,202)	(35,050)	35,683
Net Interest		28,640	3,622	(7)	(8)
Other		0	0	0	0
Profit Before Tax (norm)		12,779	(41,580)	(21,924)	35,675
Profit Before Tax (FRS 3)		12,779	(41,580)	(35,057)	35,675
Tax		22,530	6,883	6,198	(9,632)
Deferred tax		(0)	(0)	(0)	(0)
Profit After Tax (norm)		35,309	(34,697)	(15,726)	26,043
Profit After Tax (FRS 3)		35,309	(34,697)	(28,859)	26,043
Average Number of Shares Outstanding (m)		21.5	21.6	21.6	21.8
EPS - normalised (ore)		164	(161)	(73)	120
EPS - FRS 3 (ore)		164	(161)	(134)	120
Dividend per share (ore)		0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets		74,070	87,486	82,759	70,157
Intangible Assets		26,390	33,315	21,920	8,373
Tangible Assets		1,660	1,268	1,804	2,750
Other		46,020	52,903	59,035	59,035
Current Assets		212,268	175,613	140,016	179,291
Stocks		17,955	19,552	18,175	28,976
Debtors		12,323	14,573	21,048	25,100
Cash		169,239	129,368	87,925	112,347
Other		12,750	12,119	12,868	12,868
Current Liabilities		(30,637)	(40,267)	(38,729)	(38,729)
Creditors		(30,637)	(40,267)	(38,729)	(38,729)
Short term borrowings		0	0	0	0
Long Term Liabilities		(3,758)	(4,752)	(5,179)	(5,697)
Long term borrowings		0	0	0	0
Other long term liabilities		(3,758)	(4,752)	(5,179)	(5,697)
Net Assets		251,943	218,079	178,867	205,023
CASH FLOW					
Operating Cash Flow		19,193	(23,593)	(40,404)	24,907
Net Interest		0	0	0	0
Tax		0	0	0	0
Capex		(21,715)	(18,588)	(1,719)	(1,766)
Acquisitions/disposals		33,213	0	0	0
Financing		0	0	0	0
Dividends		0	0	0	0
Other		2,394	2,310	681	1,281
Net Cash Flow		33,085	(39,871)	(41,443)	24,422
Opening net debt/(cash)		(134,026)	(169,239)	(129,368)	(87,925)
HP finance leases initiated		0	0	0	0
Exchange rate movements		0	0	0	0
Other		2129	0	0	0
Closing net debt/(cash)		(169,239)	(129,368)	(87,925)	(112,347)

Source: Company accounts, Edison Investment Research

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