**Thesis:**

Cysview is gaining traction in the United States

* Unit Economics
* Reimbursement vs White Light
* What actions the company is taking to market the products

Investor Base:

Check who’s invested in the company and why is there so many institutional shares.

**Description**

Photocure ASA has been quietly taking up the bladder cancer detection industry over the past three years. In its hometown, Nordics region, the company’s key product Hexvix/Cysview has penetrated 40% of the market. Hexvix is the name used for non-US territories; and vice versa for Cysview. Hexvix/Cysview is a drug that, after taken by the patient, will mark cancer cells in the bladder and make them glow bright pink/red during cystoscopy with a blue light enabled cystoscope (Blue Light Cystoscopy, BLC™).

Currently, the company directly sells the product to Nordics and the USA regions, and license to other pharma companies to sell in the EU, Canada, and Australia.

Photocure also develops Cevira for the treatment of human papilloma virus infection and precancerous lesions of the cervix. The company had entered into a License Agreement providing Asieris Meditech Co., Ltd (Asieris) with a world-wide license to develop and commercialize Cevira.

We think the company is trading at a compelling valuation due to its microcap status and it’s listed in Norway. We believe the company can return 4x on investment in three years.

**Thesis I: Hexvix/Cysview will soon to be the standard of the industry**

Traditionally, white light cystoscopy involves a cystoscope with a lens and a white light for visualizing suspicious lesions. Once lesions are identified, the urologists can surgically remove cancerous tissues, through a procedure called a transurethral resection of the bladder tumor (TURBT). However, there is a high risk of missing tumors, especially the flat and aggressive carcinoma in situ (CIS) lesions. The BLC technology allows one to easily detect tumors that would otherwise be ignored under the white light cystoscopy. And these overlooked CIS lesions are the culprit for progressing non-muscle invasive bladder cancer (NMIBC) to muscle invasive bladder cancer (MIBC), which is a very dangerous stage where patients might die. Therefore, early identification and prevention are key to avoid this vicious progression.

The use of Hexvix/Cysview 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 who 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.

Nevertheless, having the tumors removed is not the end of the story. The recurrence rate is 61% in 1 year and 78% in 5 years. Therefore, outpatient and clinic surveillance cystoscopy is performed to monitor the bladder. The American Urology Association recommends surveillance every three to six months for the first three years after diagnosis and yearly thereafter. That would increase Cysview’s wallet share in existing patients especially given that in 2019, the FDA approved Cysview’s indication for surveillance with flex BLC devices. This extended indication will also integrate Cysview throughout the patient journey.

Ever since Cysview hit the US market, the perception has been great. This has been reflected in numerous scientific studies, journals, authority recommendations, permanent and favorable reimbursements etc. We think over time, the ease of use and the high efficiency will position Cysview with BLC as the industry standard to replace the prevalent practice of using the white light cystoscopy.

In under three years, the USA has become a significant growth driver and taken up almost half of the sales of the company. The management sees the potential in the USA and has guided $70m US sales in 2023 (vs. $11m in 2019). To increase the sales 7x under three years is a very ambitious goal. It requires the company to score a run rate of around 70,000 procedures (unit price is ~$1000 in the USA). However, we think this goal is very attainable given the addressable market of 300,000 TURBT procedures and 1.4m bladder cancer surveillance procedures. So 70k procedures is only less than 5% total penetration. US sales have been growing at 35% in the past three years, but we expect the growth to accelerate significantly because of much improved reimbursement rates and added codes.

Even COVID cannot suppress the inevitable growth. Many procedures in the US were delayed in Q1 and Q2 because hospitals needed to free up capacities for COVID-related activities. However, these couple months of delay would only mean worse cancer progression for patients, thus generating a pent-up demand. YTD sales is only 2% below last year’s level.

It’s worth noting that the company only makes the drug Hexvix/Cysview, it does not manufacture and sell the BLC devices. Instead, the task is entrusted to KARL STORZ, who makes rigid BLC for operating room setting, and flex BLC for office/clinic setting. This arrangement eases the cost burden on Photocure who has a 90%+ gross margin, and free up resources to invest in sales and marketing forces. It is important to monitor the cystoscope installations, though, because you need that device to shed the blue light on marked cancer cells. One cannot go without the other. Installations in Q1 were up 39% YoY, and 31% in Q2, all with coronavirus going on. In fact, we would argue that the COVID will accelerate the adoption of flex BLCs as they will free up hospital resources and meanwhile address the patient demand.

Asides from the $70m USA ambition, the management is also targeting NOK 1 billion total sales in 2023 with EBITDA margin of 40%. NOK 1 billion is equivalent to $111m. So, asides from the $70m US sales, the company still need $40m from the rest of the world. We think that should not be a problem. In April 2020, the company secured sales right to the EU ex Nordic region from Ipsen, to whom the company entered into a marketing agreement in 2011. Ever since then, the royalty revenue is classified as Partner Revenue on Photocure’s book. In 2019, partner revenue was NOK 65m, book sales for the partnered regions are expected to triple once it initiates sales this October. So, that’s NOK ~190 million ($21m) based on 2019 partner sales.

Currently the company has under 5% penetration in German speaking countries, DACH, and the management expect these regions to reach the same 40% level seen in Nordics. There’s virtually no penetration in UK, Spain, Italy and other countries. Furthermore, Hexvix is product that sells so well that Ipsen’s “sales reps are extremely interested in coming over and working for Photocure and selling Hexvix into the future”, according to the CEO’s dialogue with them. Given this white space, we believe the total EU sales can easily exceed $40m in 2023.

The company can achieve the NOK 1 billion from Hexvix/Cysview alone. We are not even talking about the Cevira call option here. Asieris is at Phase III in China, so it won’t be long until it starts generating royalty revenues, assuming it gets commercialization approval.

**Thesis II: Blue-Sky Competitive Environment**

Even if Hexvix/Cysview patents expire, there’s little to worry about generic erosions. Photocure continues to wrap additional IPs around the product, this will vastly limit what aspired imitators can do without infringing those IPs, therefore discouraging them from even trying. Second, because under the ATC classification, the product will be shown in the “Other Diagnostics” category, where it’s buried with many other products, therefore avoiding the spotlight.

Generic players like quick and easy stuff, but they are expected to find none on Hexvix/Cysview. The management is finalizing the EU and the U.S. Pharmacopeia monograph specifying very tight specifications around the manufacturing of the product. That would mean generic companies will have to follow a very tight recipes, which is not something they favor. Also, manufacturing the product requires freeze-dried API under aseptic conditions. It's a solvent in a vial or prefilled syringe that requires manual/semi-manual packaging and labeling. To get the API, one would have to knock on the door of the only one commercial medical-grade API supplier in the world, with whom the company has an exclusive arrangement. In short, the manufacturing hurdle is too high for imitators to even think about.

To top it off, as mentioned earlier, Hexvix/Cysview has to work with BLC devices to be useful. The drug-device combination would require complex regulatory processes where one would have to worry about ANDAs and PMAs, and work with multiple FDA offices. So, even if a generic player manages to get through the regulatory hurdles, they’d still have to work with medical device manufacturers like KARL STORZ, Wolf and Olympus, who do not have any interest to work with the generic manufacturers because their sales depend on Hexvix/Cysview acceptance, which has been great given the permanent and favorable

reimbursement policies; and healthcare providers would have no interest to switch to a generic version because their out-of-pocket pay is very low.

The company is essentially facing the largest indirect competition, namely the traditional white light cystoscopes. Photocure has superior power over the traditional method because of the ease to use and the high efficacy. Healthcare providers love the product because they will have better results from patients. Patients are happy for obvious reasons. Payors are happy because less recurrence would ease the cost burden on them. Plus, the permanent and favorable reimbursement terms make the switch a much easy process for healthcare providers. We think white light cystoscopes standard will inevitably become dated and replaced by BLC.

**Thesis III: Attractive Valuation**

Assuming management’s 2023 ambition is the most optimistic case, a 40% EBITDA margin would mean NOK 400 million. Apply a 20x 3-year average EV/EBITDA for Specialty Pharma companies, we have an EV of NOK 8 billion. The company has a net cash of NOK 450 million, so market cap, call it NOK 7 billion. With 27 million shares out, that implies NOK 259 per share, or about 3x today’s NOK 89 per share. This assumption excludes Cevira’s value (~$250m in total, estimated by the mgmt.).

More conservatively, we assume the company can only do NOK 700 million by 2023 (which is unlikely given the Ipsen transaction would bring the total sales to more than half of that, just based on 2019 numbers alone) and a 25% EBITDA margin, that would give us NOK 115 per share, or 30% upside. In the extreme downside case where the company fails to execute the growth strategy, we project a 20% organic revenue growth through 2023, a depressed 20% EBITDA margin, and a low-end EBITDA multiple of 15x, that would leave us NOK 48 per share, or a 46% downside.

Right now, the company is not generating positive EBITDA but has been FCF positive. It is trading at 6x LTM revenue. We think that’s a cheap valuation due to 1) the COVID impact on sales and 2) a potential 7x sales growth in three years.

We think that being a microcap listed in Norway severely discount the discoverability, therefore the valuation, of the stock. Through conversation with the management, we learned that they don’t have a near plan to uplist in the US. However, we think that as product continues to gain traction in the US, investors will notice the company eventually, and as the management executes, we think the valuation will rerate. More, looking further ahead, we think there’s a possibility for the company to uplist in the US given this will be the company’s major market and that the CEO is US-based, too.

The risk reward on this investment is very attractive with near to mid-term catalysts such as the Ipsen deal in October, earnings in November (to see how things going with regaining the sales in EU, the US growth, and the sales in Chile—the first South America country the company has set a foot on in August), and Cevira’s Phase III data readout (no definitive timeline).

Lastly, we think by underwriting this investment, we are also getting an M&A put option to protect our downside. Due to the pureplay nature of the firm, a net-cash position, and the small size, the company is prime as an acquisition target to add to some pharma’s portfolio.

**Risks**

* The OTC version of the stock is not very liquid and common stock listed on the Oslo exchange require brokerage access, which may incur higher fees for commissions and forex exchange.
* The transition to regain EU sales from Ipsen will impact SG&A and the transition might not be smooth. However, we think the company already has the experience and the infrastructure built up by Ipsen; and the transition to direct sales will also get help from existing Ipsen sales reps who are keen to make commissions off Hexvix.
* Cevira might fail the Phase III trial, but we view it as an unlikely event as previous data readouts have proven a safe profile and a strong efficacy. More, it’s a call option, if it fails, the fundamental story of the company does not change.
* Decline in partner sales. Asides from the EU, the company entrusts sales to Juno and BioSyent for Australia/New Zealand and Canada, respectively. Two years ago, these regions experienced delay in scope installations. But we think these are reputable and powerful partners and the delay has been resolved as the reimbursement policy adapted the BLC devices. It’s worth mention that BioSyent has been a 100-bagger and the CEO who led the growth is still with the company. We trust BioSyent’s CEO’s extensive knowledge and network with Canadian sales and distribution channels.
* Regulatory changes with respect to coding and reimbursement. This was happened in France where Hexvix experienced a loss of reimbursement in 2018, which was perplexing because new French National Guidelines for bladder cancer recommended the use of blue light cystoscopy for the first bladder resection in almost all patients. But we think that as Hexvix/Cysview gets gradually accepted as the industry standard, countries will follow America’s playbook to adopt better reimbursement to the product.

**Catalysts**

Regains EU sales right from Ipsen in October

Earnings release in November

Cervira Phase III data readouts in China

New sales/distribution agreements in new territories

This writeup—will increase people’s awareness of the company

**Appendix**

<https://photocure.com/news/new-commercial-strategy-for-hexvix/> [2011 agreements with Ispen]

<https://www.karlstorz.com/cps/rde/xbcr/karlstorz_assets/ASSETS/3577509.pdf>

[Karl STORZ data on 2 Part device]

<https://www.globenewswire.com/news-release/2015/08/19/1041585/0/en/BioSyent-Pharma-Acquires-Exclusive-Rights-For-Cysview-R-In-Canada.html> [BioSyent deal]

Juno deal

**Questions**

US – is pricing the same for surveillance vs TURBT?

How do you get your goal by 2023? Understand that the total addressable market is huge, but what hurdles do you see that would delay your expansion in the US?

For BLC machines, do you make any money out of these? How does the partnership work with manufacturers?

Seems like no. but BLC installation would be an important metric to monitor as every new installation would mean a lot to the sales. So in 2019 there were 223 total BLCs. So each BLC roughly generates MNOK 1. Should we see the per unit value to increase due to better reimbursement? ~~Also, it is also included in the surveillance indication as well, that would generate more unit value.~~

~~So, flex is for surveillance setting. We can expect the unit value to reach MNOK 1.6 as there’s 60% recurrence in 1 year. Just using the 2019 sales, this expansion to surveillance indication would imply MNOK 356.~~

Overall strategy on geographical expansion: can we use what’s going on with Ispen as a playbook for other regions?

Does this really matter? If the USA region reaches MNOK 600, and EU ex Nordics achieve MNOK 200, then it’s already a 4x return on investment. So our underwriting would actualize 40% IRR for three years, that is just to assume no multiple expansions. So, we can make a case that even with the conservative estimate, this should be a sound investment. But why the stock is still no recognizing it? The institutions are buying but that did a little to the stock price. What is happening?

So is this for preventive measurements only? Can MIBC patients still use this?

It appears to be so. The goal is to identify tumors that usually led to MIBC progression because they are flat and hard to detect using white light cystoscope.

Ispen – what is the impact on SG&A?

Profitability? The management expects the Ispen deal to be EBITDA accretive, but not positive, for the full year 2021. So, I think there’s still danger for this investment. This thing is not gonna be profitable anytime soon. I guess I need to see how the Ispen deal executes in Q3 and ask some questions about spendings. But I can probably write it up for VIC.

**USA**

Right now they only have 11000 procedures. This was slow because of the reimbursement issues. But CMS and other health institutions are very supportive of this product because it can ease the burden on the cost system. So we are betting on if they can 7x the procedures by 2023.

So, USA will be a key driver behind the growth. Right now, people are discounting the stock because the company’s lack of access to hospitals given the COVID dynamic. However, things are opening up and more installations are built for flex settings. I think the investors are just not paying much attention to the stock in general given its microcap and Norway-listed nature.

Bladder cancer occurs mainly in older people. About 9 out of 10 people with this cancer are over the age of 55. The average age at the time of diagnosis is 73.

So, what are the variables here?

* Reimbursement—this should be okay as people are well aware of its obvious benefits. I think that will only improve in the foreseeable future.
* New installations as well as flex (have to monitor how KARL STORZ perform)

 large untapped potential in the European market, worth EUR 150 million

sleep very, very well because of these 5 reasons. And this is why I believe that generic manufacturers have no interest nor ability to either develop this product or market it or even understand what it does. And I'll give you the 5 reasons. The first 1 is from an IP intellectual property standpoint, we have and we will continue to wrap IP around our products. And from a generic manufacturer standpoint, when they look at a product to genericize, they don't want to see a lot of extra intellectual property around the product. That makes them a little unnerved that they are going to violate some patent and that their efforts would go to waste. That's number one. Number two, from a desk research and market size perspective, this product can't be found through syndicated databases. In other words, if they look up into just general access to data, Cysview or Hexvix does not show up. It's ATC classification is other diagnostics. So it's mixed in a giant basket. So it doesn't stick out is a real opportunity. It's not like a glowing light. It's mixed up. They would have to actually get on our website and really dig into the data to figure out what the product potential might be from a generic standpoint. Second thing -- third thing is technical and manufacturing hurdles. We're in the process of finalizing the EU and the U.S. Pharmacopeia monograph specifying very tight specifications around the manufacturing of the product. And this is -- just makes it much harder for generic manufacturers. They do not like to follow very tight recipes, and that's exactly what we intend to do. The product itself, generic manufacturer wants something fast and quick and easy, and it's not fast and quick and easy. It's freeze-dried API under aseptic conditions. It's a solvent in a vial or prefilled syringe it's manual and semi manual, packaging and labeling. It's not press pills and push out the door. This requires effort and generic manufacturers don't want to put that kind of effort behind the product of this type. And I think the final thing is we do have the exclusive arrangement with the only commercial medical-grade API supplier in the world. So they would have to actually go out and find a manufacturer to supply commercial-grade API. Fourth, regulatory hurdles. This may be 1 of the larger ones for them in terms of hurdles. It's the drug-device combination that dissuades displays, generic manufacturers, they don't want to get in the situation where they're having to worry about ANDAs and PMAs and work with multiple FDA offices. In fact, they would have to work with the capital equipment manufacturers themselves, Karl STORZ, Wolf and Olympus. I can tell you that they have no interest to work with the generic manufacturers because they see real value in a company like Photocure, who will continually service and support Blue Light cystoscopy The generic manufacturers are not going to put a sales force out to sale services we're a very strong partner with our capital equipment manufacturers, and they wouldn't want to damage that relationship.

. So what we focused in on is contacting Ipsen and Ipsen sales forces there. And I would very pleased to tell everyone that their sales reps are extremely interested in coming over and working for Photocure and selling Hexvix into the future that I've had video conferences with them, my general managers work with them

installation is very important. I don’t know if this model can be sustainable. They should be. Physicians want to have the product to improve their accuracy and reputation. But they can’t just do it with the machine alone. They have to purchase the consumables for the whole thing to work.

Seems like the organic growth rate is pretty slow. The company’s major source of growth comes from signing partnerships and out-licensing. However, the growth was probably depressed by the lack of access to some other regions. The USA sales growth has been solid. Nordic growth has been plateaued but there’s white space in DACH and UK countries, as well as Asia.

Total revenue reached NOK 281.6 million up from NOK 181.5 million in 2018. Revenues were mainly driven by significant revenue growth in U.S., as well as signing fee payments and committed milestones from Asieris for Cevira. Also revenues from Nordic and partner revenue have increased from 2018.

Sales revenues reached NOK 213.9 million in 2019, an increase of NOK 40.7 million from NOK 173.2 million in 2018. Sales revenues comprise own sales of Hexvix® in the Nordic region and Cysview® in the U.S. and income from product sales and royalties from Photocure’s license partners on sales of Hexvix® to hospitals and pharmacies in other regions.

Signing and milestone revenues totaled NOK 67.6 million in 2019 compared to NOK 8.3 million in 2018. Signing and milestone revenues include signing fee payments and committed milestones from Asieris for Cevira of NOK 65.1 million in 2019 and milestones from Bellus Medical totaling NOK 4.9 million in 2018. Furthermore, the signing and milestone revenues include revenues from the partner agreement with Ipsen.

**Cevira agreement with Asieris**

Under the License Agreement, Photocure has received a total signing fee of USD 5.0 million during 2019. In addition, the company may receive a total of USD 18 million based upon achievement of certain clinical and regulatory milestones in China and up to USD 36 million for certain clinical and regulatory milestones in the U.S. and EU. Approval of a second indication in China, the U.S. and the EU would result in payments of up to USD 14 million. Sales milestones and royalties of 10% to 20% will apply in all markets.

**Market**

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Step 2 is the expansion, both geographic expansion, which Chile is an example. We're looking at Asia, South America, other European countries that Ipsen had control of that elected not to expand into. And also the -- enhancing the value of Hexvix and Cysview, and this is through things as far as investigating the therapeutic use or enhancing the detection or the usability of the product.

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**Ispen transition**

So they had this agreement in 2011 where PHO allows Ispen to market and sell products in the rest of world ex US and the Nordic region.

So, how do you think about the growth? If they can execute as expected, we should see a really good return. As the products become standard of the industry practice, the company will dominate the market with consistent recurring revenues from the surveillance segment where a patient might go through multiple times of check-up to monitor the bladder.

What could go possibily wrong? Well, as Ispen hands over the commercialization right, we are not sure if the mgmt. has the experience or relationship to continue to sell the product in the rest of the world. If they fail to execute, I guess they have to rely on the US market to drive the growth. Currently, the company has 5-10% of US penetration with 35% growth rate YoY. So, total sales revenue might have an organic growth of 20% factoring in the Nordic regions. 20% growth is not bad but would make this investment an expensive underwriting.

Photocure’s book sales for the partnered regions are expected to triple (2019 royalty was NOK61m excluding IFRS adjustments) once it initiates sales though there will also be an impact on expenses – how much is the SG&A impact?

Photocure would need to have an annual procedure run rate of around 70,000 in an addressable market with 300,000 TURBT procedures and 1.4m bladder cancer surveillance procedures (less than 5% total penetration

**Hexvix/Cysview**

The addition of Hexvix/Cysview was shown by Photocure in its clinical trial programme to detect tumours that white light misses (see Exhibit 2). In total, 16% of patients had Ta (non-invasive papillary carcinoma) or T1 (cancer that invades from the surface epithelial layer into the connective tissue) tumours that were missed by the white light standard of care and were only detected through the use of Hexvix/Cysview. This is quite meaningful as bladder cancer is one of those cancers where there is a big difference between five-year survival rates for cancers that are caught early and those that are caught late. According to the National Cancer Institute, the five-year survival rate for those with localised cancer is 69.9%, 34% for those with regional and 5.4% for those where the cancer has distant metastases.

The AUA recommends surveillance every three to six months for the first three years after diagnosis and yearly thereafter.

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 who 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.

Another driver of US growth is improved reimbursement. Prior to 2018, CMS did not separately reimburse centres for use of the BLC with Hexvix/Cysview procedures, but instead bundled it with the total reimbursement for transurethral resection of bladder tumour (TURBT) procedures so any additional cost related to the product was absorbed by the centre. This has had a direct impact on the availability of BLC with Hexvix/Cysview in the US. Starting in 2018, there was a separate code for BLC with Hexvix/Cysview, which improved reimbursement in 2019 and will further improve in 2020.

Best option for decreased recurrence per AUA/SUP guidelines

**Cevira®**

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