

Photocure ASA

DNB Virtual Healthcare Conference 2020

15 December 2020

Daniel Schneider, President and CEO

Erik Dahl, CFO



THE
BLADDER CANCER
COMPANY

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Global commercial-stage bladder cancer specialist headquartered in Oslo



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Direct sales in
U.S. & Europe
with worldwide
partnerships

**NOK
281.6M**
total company
revenue 2019

Approved for
use in
**~30
countries**

**~100
employees**

**>500K
patients**

Symbol: PHO (OSE)
Market Cap*: NOK 2,268M
Shares Outstanding: 26.3M
ADTV*: 215K last 30 trading days

* Market data as of 11 December 2020

Bladder cancer has been chronically underserved



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COMMON (6th most common cancer worldwide¹)

550K
new cases
annually¹



200K
deaths annually
of which 75%
are men¹

EXPENSIVE

Highest
per patient
lifetime
treatment
costs of any
cancer²



**USD
5.7B**
Cost of Bladder Cancer
in the U.S., projection
for 2020³

RECURRENT

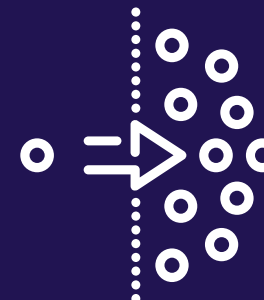
Up to
61%
Recurrence
in 1 year⁴



Up to
78%
Recurrence
in 5 years⁴

PROGRESSIVE (FROM NMIBC TO MIBC, at 5 years)⁴

1%



45%

1) Globocan. Incidence/mortality by population. Available at: <https://gco.iarc.fr/today>, accessed [December 2019]. 2) Sievert KD et al. World J Urol 2009;27:295–300 and Bladder Cancer. American Cancer Society. <https://www.cancer.org/cancer/bladder-cancer.html>. 3) Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, Brown ML. Projections of the cost of cancer care in the United States: 2010-2020. J Natl Cancer Inst. 2011;103(2):117-28. 4) Sylvester RJ et al. Eur Urol 2006; 49:466-467 Global Data: Bladder Cancer Report

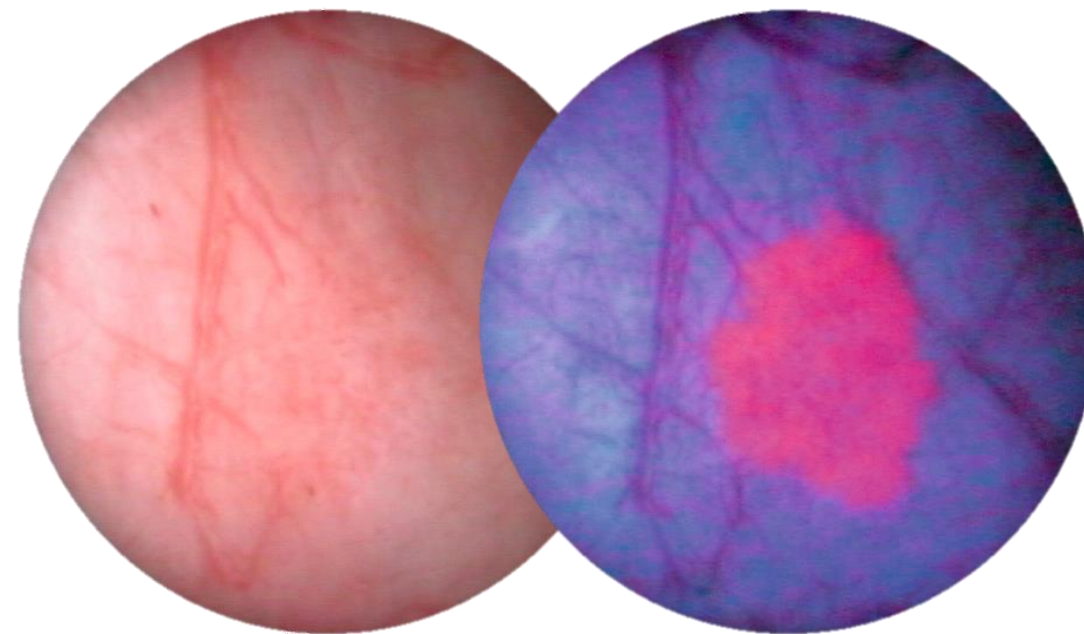
Blue Light Cystoscopy: Creating a New Standard of Care “You cannot treat what you cannot see!”



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Improved detection vs. white light cystoscopy alone^{1–4}

- Hexvix[®]/Cysview[®] is a drug that preferentially accumulates in bladder cancer cells, making them glow bright pink during blue light cystoscopy⁵
- Hexvix blue light cystoscopy offers improved detection during surgery and surveillance leading to a reduced risk of recurrence vs. white light cystoscopy alone^{1–4,6–9}
 - Hexvix/Cysview detected **21% of recurrent patients** that were assessed as disease-free under WLC alone in follow-up/surveillance of non-muscle invasive bladder cancer (NMIBC)²
 - In the OR, Hexvix/Cysview found **35% of patients with CIS** (high grade NMIBC) that were missed with WLC alone²



Bladder cancer seen under white light (left) and using Hexvix[®]/Cysview[®] blue light cystoscopy[®] (right)
- Courtesy of Professor Dirk Zaak; Traunstein, Germany.

HEXVIX[®]
Hexaminolevulinate 85mg

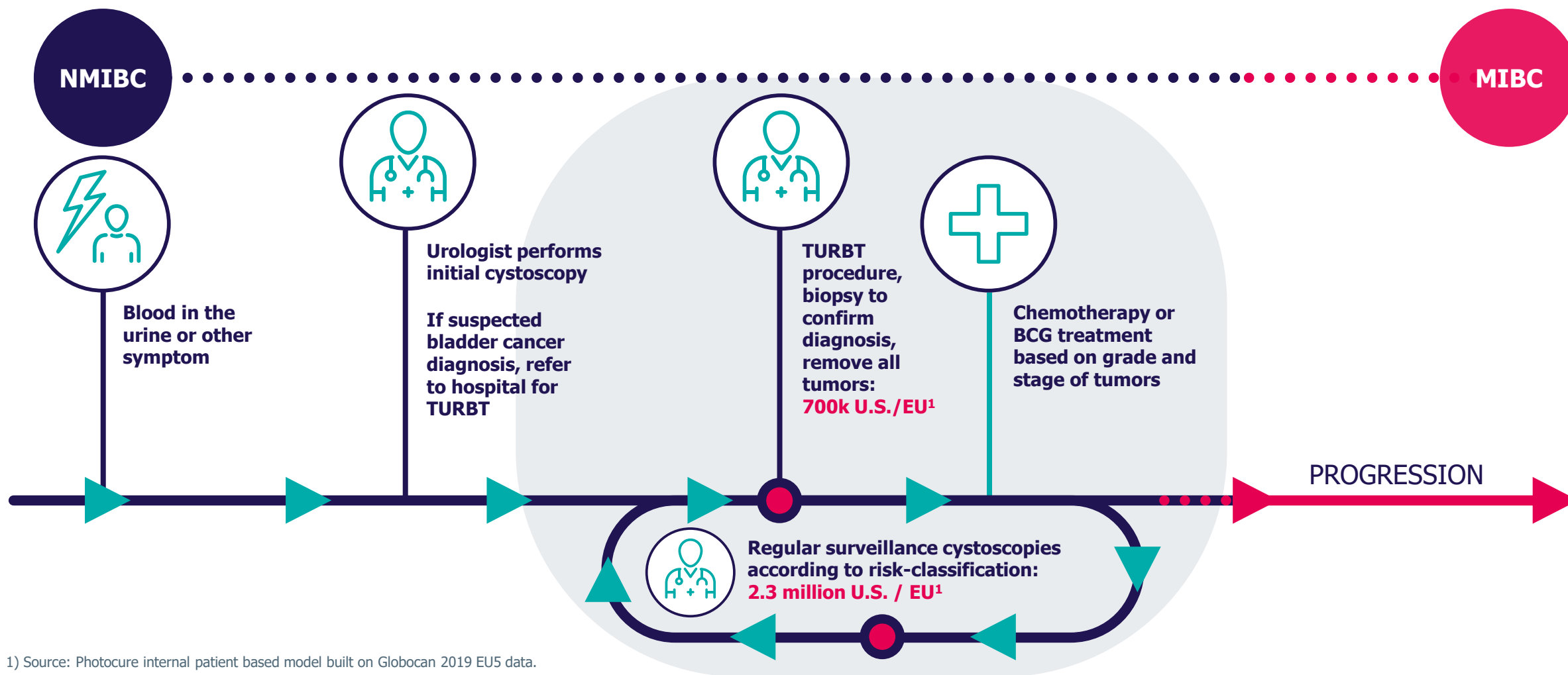
CYSVIEW[®]
Hexaminolevulinate HCl

Summary of product characteristics: <https://www.hexvix.com/safety-information/> / **Cysview prescribing information:** <https://packageinsert.s3.us-east-2.amazonaws.com/Cysview+PI+2020.pdf>
References: 1. Hermann GG et al. *BJU Int* 2011; 108(8 Pt 2):E297–E303. 2. Daneshmand S et al. *J Urol* 2018; 199(5):1158–1165. 3. Stenzl A et al. *J Urol* 2010; 184(5):1907–1913. 4. Burger M et al. *Eur Urol* 2013; 64(5):846–854. 5. Hexvix[®] (hexaminolevulinate hydrochloride) 85 mg Summary of Product Characteristics. 2019. 6. Drejer D et al. *Urology* 2020; 137:91–96. 7. Gallagher KM et al. *World J Urol* 2017; 35(12):1871–1877. 8. Geavlete B et al. *BJU Int* 2012; 109(4):549–556. 9. Grossman HB et al. *J Urol* 2012; 188(1):58–62.

The Patient Journey: Characterized by long term follow-up with repeat procedures



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1) Source: Photocure internal patient based model built on Globocan 2019 EU5 data.

Increasing media attention for the BLC[®] procedure and bladder cancer



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[UroToday Home](#) > [Video Lectures](#) > [Bladder Cancer Expert Debates](#) > [Video](#)

Blue Light Cystoscopy with Cysview[®] & Adjuvant Perioperative Chemotherapy for Nonmuscle-Invasive Bladder Cancer - Sia Daneshmand & Trinity Bivalacqua

Ashish M. Kamat, MD, MBBS
Professor, Department of Urology, Division of Surgery, The University of Texas MD Anderson Cancer Center, Houston, TX

Siamak Daneshmand, MD
Associate Professor of Urology, Director of Clinical Research, Keck School of Medicine of USC, University of Southern California, Los Angeles, CA

Trinity J. Bivalacqua, MD, PhD
R. Christian B. Evenson Professor of Urology and Oncology, Director of Urologic Oncology at the James Buchanan Brady Urologic Institute, Johns Hopkins Medicine, Baltimore, MD

URO TODAY **GU ONC TODAY**

0:00 / 27:07

UroToday 11 and 24 June, 13 September 2020

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TURBT Quality Indicators and Access Issues in the United Kingdom - Param Mariappan & Prashant Patel

Bladder Cancer

Ashish M. Kamat, MD, MBBS
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Param Mariappan FRCS(Urol), PhD
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Prashant Patel MBBS, MS, FRCSed, FRCSed (Urol), PhD
Senior Lecturer, Consultant Urological Surgeon, Institute of Cancer and Genomic Sciences, University of Birmingham

URO TODAY **GU ONC TODAY**

0:00 / 29:20

Macro and Microeconomics of Blue Light Cystoscopy with CYSVIEW[®] in Non-Muscle Invasive Bladder Cancer - Stephen Williams

Bladder Cancer

Macro and Microeconomics of Blue Light Cystoscopy with CYSVIEW[®] in Non-Muscle Invasive Bladder Cancer

Stephen B. Williams, MD
Medical Director for High Value Care, UTMB Health System

URO TODAY **GU ONC TODAY**

0:00 / 9:01

24 September 2020

How Do I Do Office Cystoscopic Fulguration?

Continued from page 24

Bladder cancer is associated with a high risk of recurrence and progression to muscle invasive disease. Due to these risks, urologists appropriately recommend cystoscopic surveillance for these patients. However, standard office white light surveillance cystoscopy (WLCS) is not without its nuances and is far from a perfect surveillance modality.

Many patients with intermediate or high risk bladder cancer receive intravesical therapy to reduce the risk of recurrence per guideline recommendations. Intravesical therapy, however, has the potential for a red patch presents a particular challenge as there is a particular fear of missing carcinoma in situ (CIS).

Some et al found that only 12% of red patches biopsied in bladder cancer surveillance patients actually represented malignancy.¹ and subsequent studies have shown that the vast majority of red patches biopsied with rigid or flexible

and/or ablation is considered a core treatment of management in endoscopic treatment of bladder cancer, which has an effect on recurrence-free and progression-free survival. Studies addressing this issue over time to the widespread use of blue light cystoscopy have found comparable oncologic outcomes between in-office biopsy and fulguration in patients with lesions smaller than 1 cm with low concern for muscle invasive disease.² Furthermore, in-office biopsy has the benefit of helping patients avoid the risks of general anesthesia. The cognitive effects of general anesthesia can disproportionately manifest in elderly patients who comprise the majority of bladder cancer diagnoses.³

Some practitioners may have hesitation about the notion of in-office biopsy from an oncologic perspective. Complete tumor resection

After 1 hour the patient voids, and is brought to the procedure room and draped in the usual fashion for office cystoscopy with a RIF. Flexible cystoscopy. Sterile water is the preferred fluid for the procedure. A systematic WLCS is performed followed by a systematic BLC. Lesions that are intermediate or high grade are immediately viewed under blue light settings to evaluate for areas of enhancement under blue light (Fig. 1).

It can be difficult to biopsy cystic spots, so the urologist can use the adjusted scope to biopsy the lesion.

The urologist can use the adjusted scope to biopsy the lesion.

URO TODAY **GU ONC TODAY**

0:00 / 29:20

September 2020 25

Office Cystoscopic Fulguration

Continued from page 24

Whole office biopsy will often yield benign results. It is not an optimal staging modality and muscle is rarely obtained. In addition, while it is highly tolerated it can be quite uncomfortable for those with bladder neck and ureteric lesions. These patients may prefer an alternative.

Despite its limitations, office biopsy is feasible, cost-effective, oncologically reasonable and has a low risk of complications. Early experience with blue light flexible cystoscopy in this setting has improved detection of high grade disease and improves office biopsy and fulguration. Further studies are needed to evaluate cost and determine the optimal patient for office blue light cystoscopy, biopsy and fulguration.

1. Ching H, Bannan GS, Chou R et al. Bladder cancer surveillance with office cystoscopy. *J Urol* 2010; 184: 1021.

2. Wang M, Szymanski S, Hanchey A et al. Random red patches seen during cystoscopic surveillance of bladder cancer: need for reoperation and other clinical factors? *J Endourol* 2015; 29: 111.

3. Kucuk D, Lee J and Lee Y. Cystoscopic office-based biopsy and endoscopic fulguration of low risk non-muscle invasive bladder cancer using office-based fulguration. *J Endourol* 2015; 29: 111.

4. Jackson H, Wager E, Wagner T et al. Second recurrence and recurrence of bladder cancer after office-based fulguration: a prospective study of cystoscopic fulguration. *J Endourol* 2015; 29: 111.

5. Wang M, Szymanski S, Hanchey A et al. Random red patches seen during cystoscopic surveillance of bladder cancer: need for reoperation and other clinical factors? *J Endourol* 2015; 29: 111.

6. Jackson H, Wager E, Wagner T et al. Second recurrence and recurrence of bladder cancer after office-based fulguration: a prospective study of cystoscopic fulguration. *J Endourol* 2015; 29: 111.

AUA News article Sept 2020

Gjør kreftcellene synlige

Det norske selskapet Photocure gjør et svært viktig bidrag til behandlingen av blærekreft-pasienter. Produktet deres selges snart over hele verden.

Tekst: Espen Aul, Bente Petrus

For blærekreftpasienter har det ikke kommet noen nye medikamenter, siden de begynte å bruke den gamle tuberkulosemedikamentet BCG. Dette til tross for at blærekreft er den sjette hyppigste kreftformen i Norge. Selv om linje har skjedd når det kommer til immunterapi og Check Point studier på dette feltet, har ikke Photocure trukket frem for store valg bidrag for blærekreftpasienter, følger Jonas Einarsson som er administrerende direktør i Radiumpolis helsekonferanser, i tillegg.

– Photocure var et av de færreste selskapene vi møtte, da det så dagens lys i 2019. De fokuserer på blærekræftdiagnostikk, noe som er et svært viktig bidrag for å kunne gi en bedre behandling til blærekræftpasienter. Produktet til Photocure brukes snart over hele verden, påpeker Einarsson.

– Hva gir dette produktet utgangspunkt for?

– Det består av et kjemisk stoff som lyser opp ved en spesiell type lys. Dette stoffet kan den egenskapen at det blir tatt opp av kreftceller, men ikke av normale celler. Dette gir rett til kjernen av lys som har vært en av de mest utford-

ringene når det kommer til blærekræftbehandling: Hvis vi ikke finner dem veldig tidlig, når kreftcellene ligger helt flatt i overflaten på blæren, er diagnosen veldig god. Hvis kreftcellene derimot forlir oppdaget og går gjennom hudlaget i blæren og inn i muskulaturen, er det en mye mer alvorlig og farlig sykdom.

– Hvis det Photocure kan med sitt produkt, bruke man vanlig brennlys når man titter inn i blæren for å se om det var kreftforandringer der. Så man kan kreftmedisiner like de selvfølgelig fjernes, men det var derfor mye som ble overrettet, forklarer Einarsson.

Det kjemiske stoffet hecotox (kalt Cysview i USA og Canada) settes inn i blæren en time før den skal undersøkes, og tar opp av kreftcellene. Så man går inn med titrert stoff og med brennlys, slik disse over til blitt lys – da lyser også kreftcellene opp som og prikker. Slik blir oppdagelsen av slike flate tumorer mye større, fordi man rett og slett ser de mye bedre. Man får dermed mye mer av kreften og tuberkulosemedikamentet blir mye mindre, forteller Einarsson.

Blærekreft kjennetegnes av hyppige tilbakefall. Ingen annen kreftform har så stor sats på langtidsoverlevende pasienter som blærekreft (cytologisk) og behandles med kirurgi, cellegift eller immunterapeutisk terapi, noe som legger stor trykkløse på blærekræftbehandling og diagnostikk.

– Har 70 ansatte, hovedkontor i Oslo og datterselskapet Photocure Inc. i USA. I tillegg er det Canada, Australia har Photocure etablert partnerskap.



Photocure

- Er et norsk farmasøytisk selskap som utvikler og kommersialiserer legemidler til bedre diagnose og behandling av pasienter med blærekræft.
- Har 70 ansatte, hovedkontor i Oslo og datterselskapet Photocure Inc. i USA. I tillegg er det Canada, Australia har Photocure etablert partnerskap.

Bladder seen through a cystoscope under blue light. Courtesy of Professor Dr. Zaki, Trautwein, Germany

URO 11-2-2020 17

Norwegian patient association magazine Sept 2020

Supportive environment for becoming the standard of care for the detection & management of bladder cancer

Recommended in global & national guidelines:



NICE National Institute for Health and Care Excellence



Thousands of bladder cancer patients worldwide have benefited from our breakthrough product



THE
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Leading positive change through:



A single-minded focus on one therapy area



Ongoing collaborations and research



The passion and commitment of our people

Commercial Organization Dedicated to Bladder Cancer Management

- Two Direct Sales Teams: Management and Field Force ~35 in U.S.; ~25 in Major EU Countries
- Distribution/Marketing Partnerships in Canada, Chile and Australia/New Zealand

U.S.: Continued blue light cystoscope placements

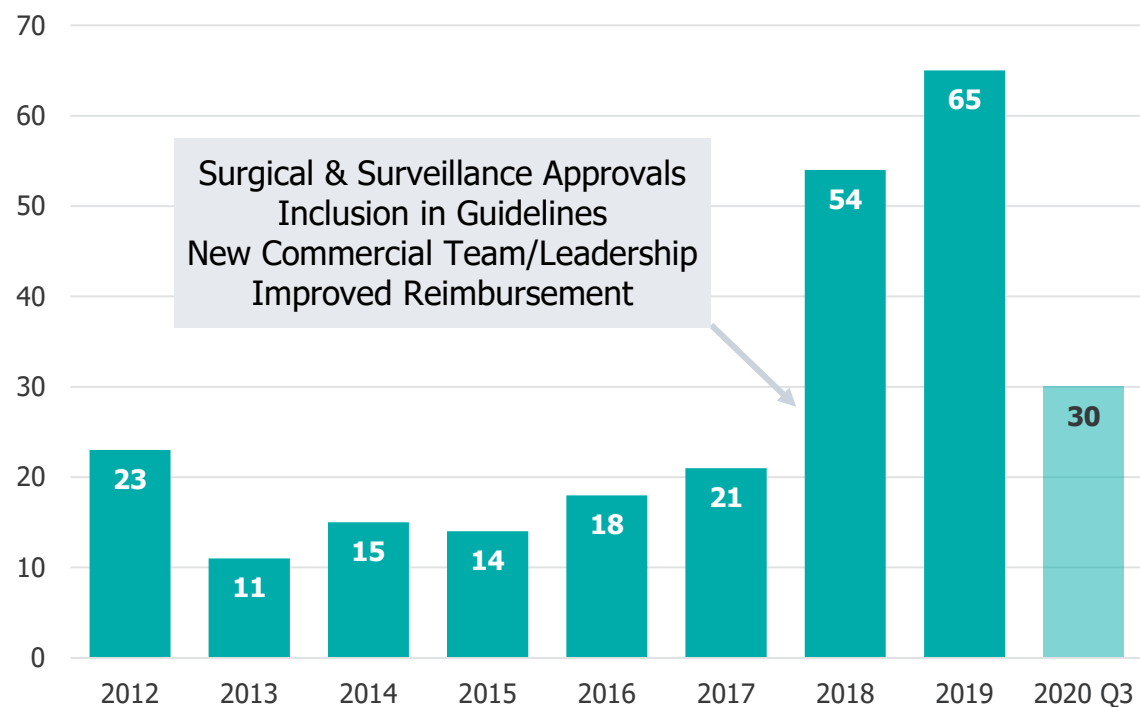
despite challenges of pandemic



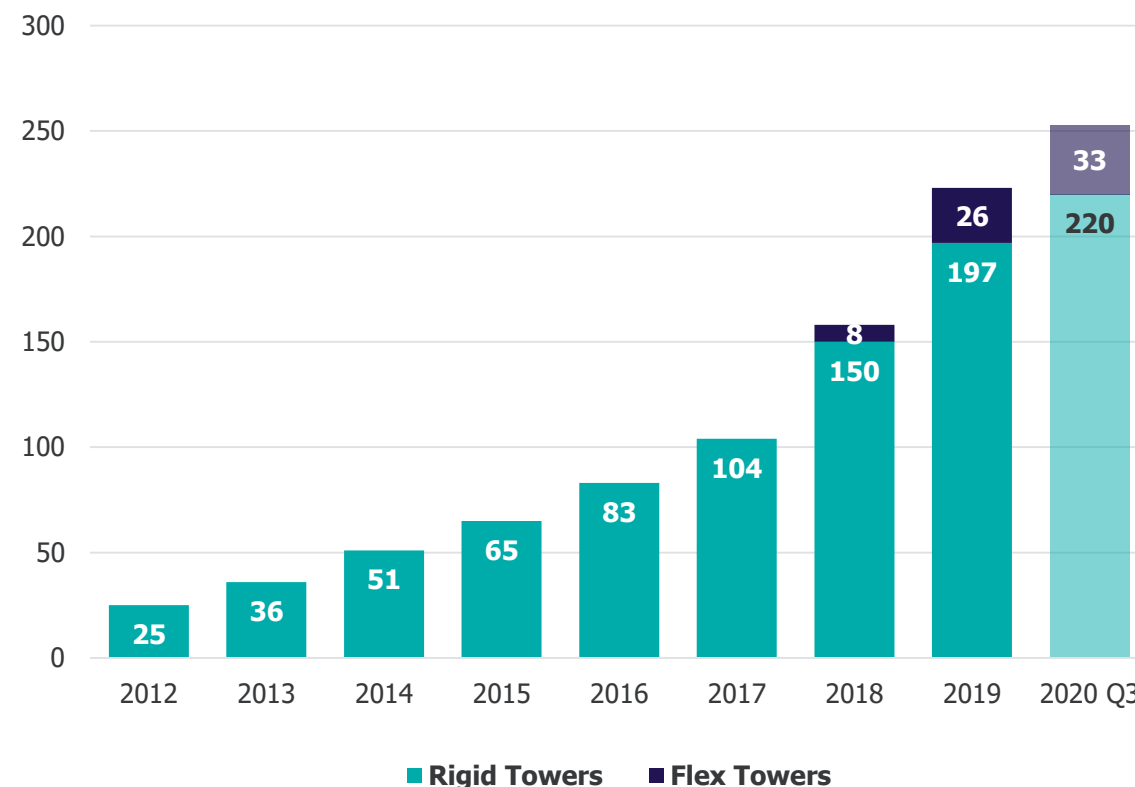
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Annual New Installations

Tower placements by year



Cumulative install base continues strong trend



*2012 – 17 of the 23 installations were converted clinical sites upon Cysview approval

Highlights in the 3rd quarter 2020:



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+20%

U.S. Revenue
Growth

+14%

Hexvix/Cysview
Revenue Growth
(adjusted)

**European
operations
live on
1 October**

**Partnership
news:**

Cevira: 1st Phase 3
patient dosed in China

Genotests: Hexvix
partnership in Chile

HEXVIX[®]
Hexaminolevulinate 85mg

CYSVIEW[®]
Hexaminolevulinate HCl

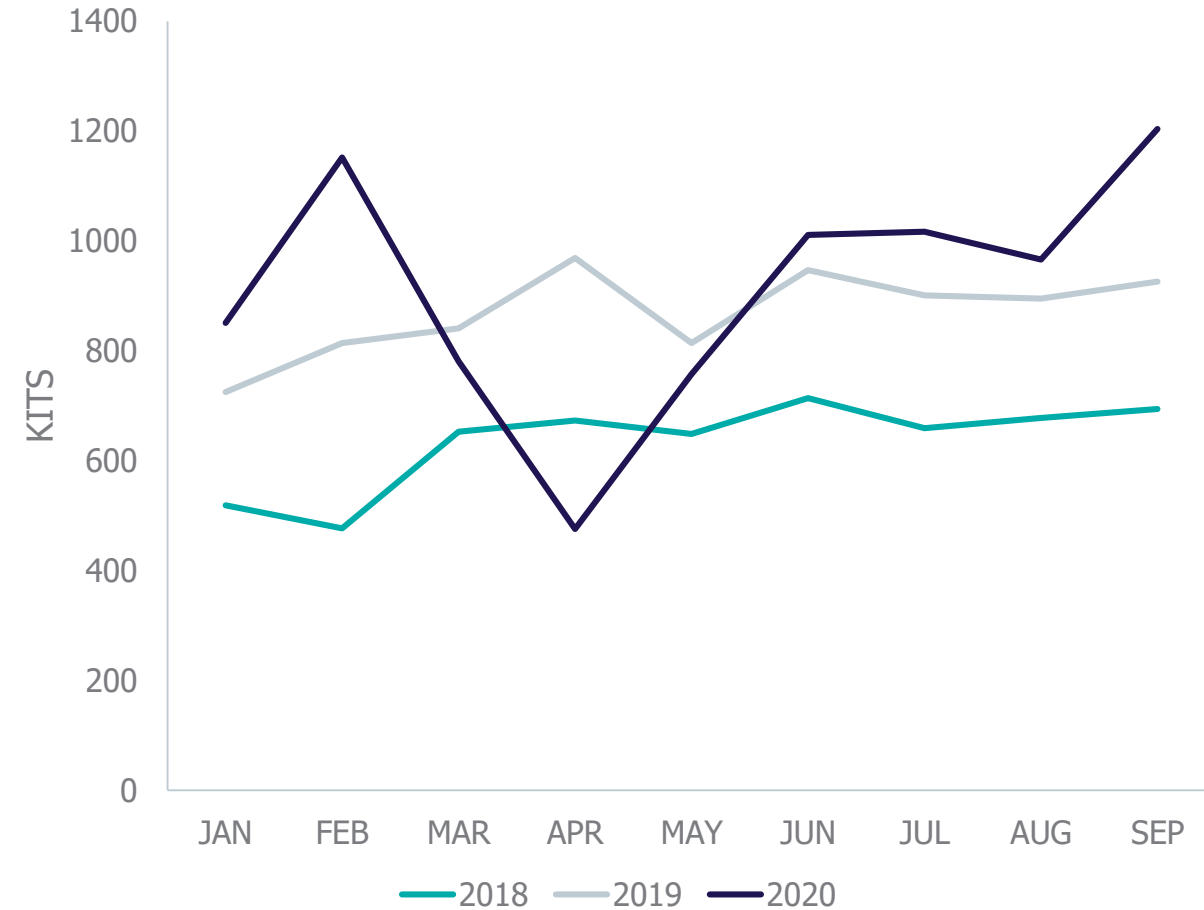
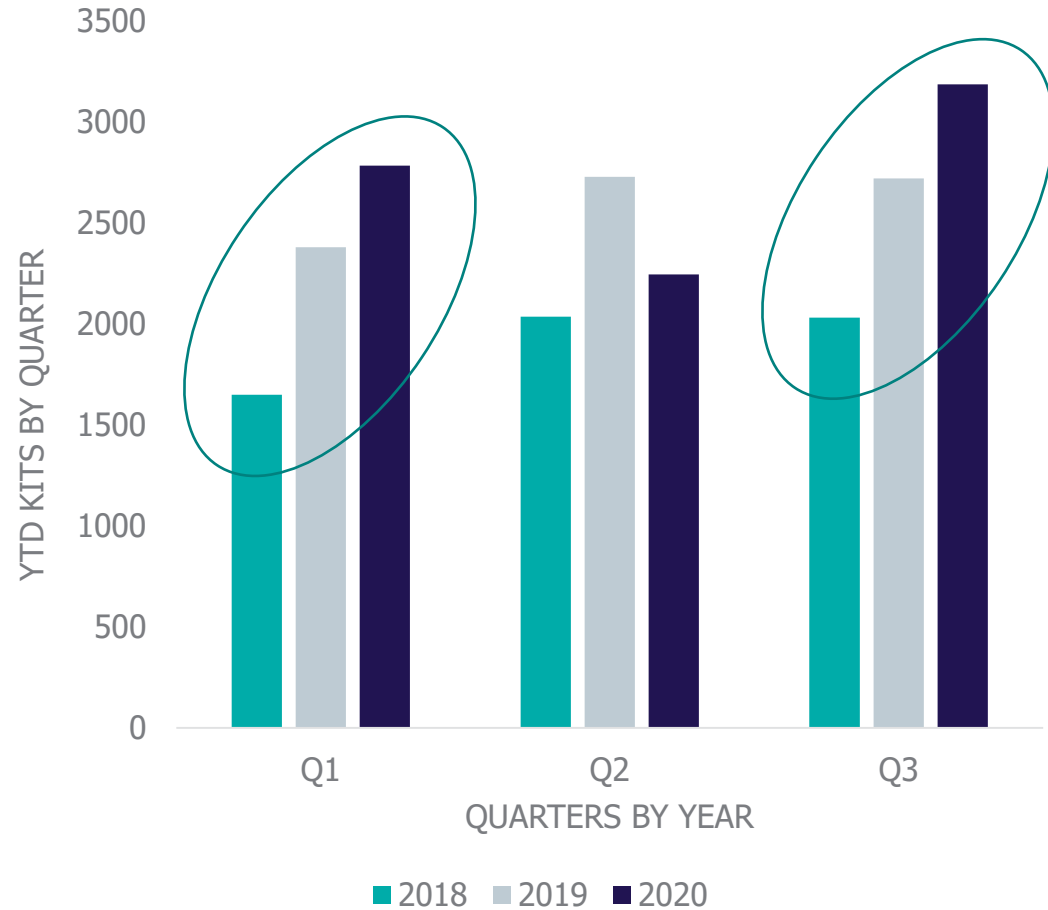
Cash balance end of Q3 2020: NOK 322M

Signs of recovery in U.S. to prior growth trend

Q3 resurges with 17% unit growth from Q3 2019 amidst Covid-19



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Launching Hexvix® Operations in Europe

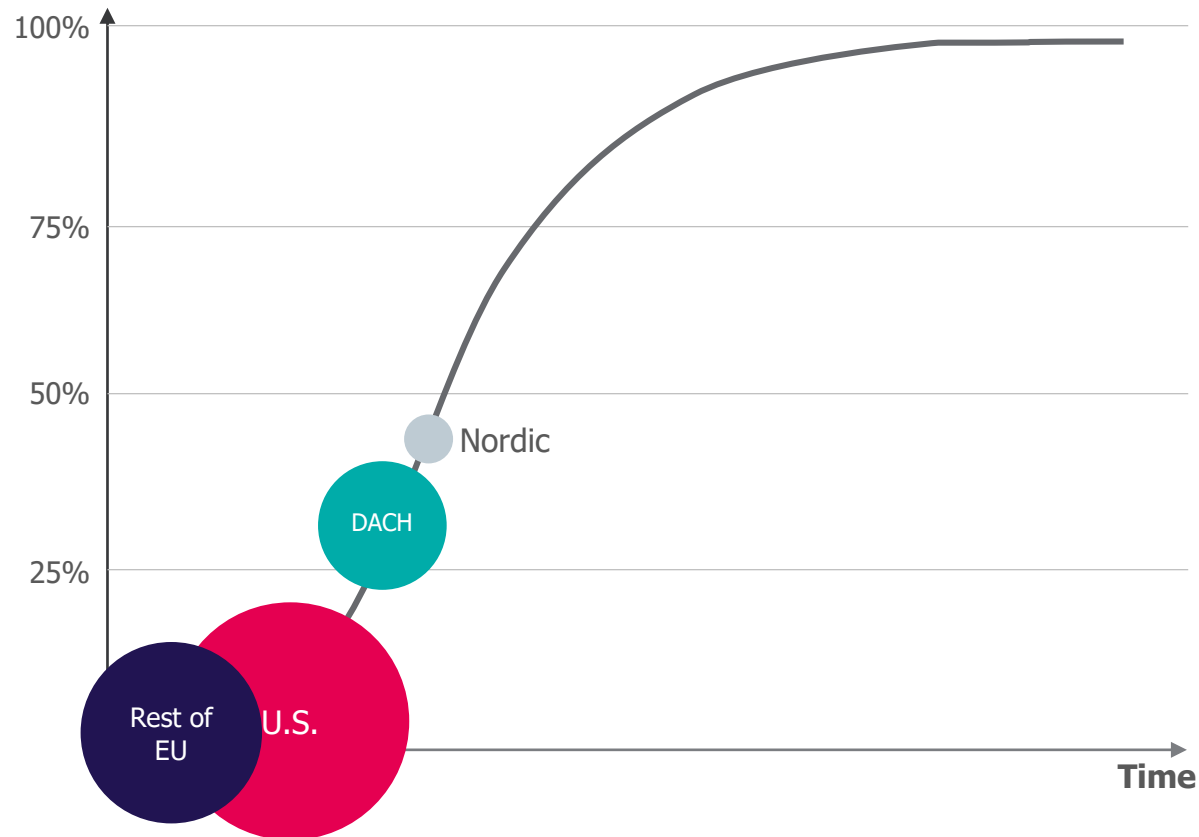
- Adds ~NOK 120M, or nearly 50% more revenue to Photocure's revenue base in 2020
- Key commercial resources in place and direct promotion initiated on 1 October
- 100% of previous Ipsen DACH Hexvix sales force now employed by Photocure ensuring no disruption in service and support
- Distribution channels built across all of Europe



Hexvix®/Cysview® – key market enablers in place: ready for growth and our ambition to become the standard of care

POSITION IN THE LIFE CYCLE

Penetration



*AUA, EAU, SUO, AFU, NICE, DGU guidelines

KEY SUCCESS FACTORS

APPROVAL



SURGICAL & SURVEILLANCE

ACCEPTANCE



MAJOR & LOCAL GUIDELINES*

ACCESS



PERMANENT AND FAVORABLE REIMBURSEMENT

"ACTIVATED"
AWARENESS



PATIENT DEMAND VIA ADVOCACY GROUPS AND MEDIA

ACCELERATE



COMMERCIAL INVESTMENT TO OPTIMIZE THE OPPORTUNITY

CEVIRA®: Value From License of Non-Core Asset to Asieris



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Asieris is a Chinese subsidiary focused on genito-urinary diseases, with their own product candidate in clinical development in China and the US for the treatment of NMIBC 1B

CEVIRA® – CERVICAL CANCER

- Breakthrough, single use, integrated drug-device technology.
- Potential to fill high unmet need for non-surgical treatment of HPV/CIN populations
- Potential to treat high grade cervical dysplasia independent of HPV genotype



License Agreement terms: USD 250M potential in total:

➤ USD 5M UP-FRONT SIGNING FEE

➤ USD 18M FOR APPROVAL OF 1ST INDICATION IN CHINA (EST 2024) AND USD 36M FOR APPROVAL OF 1ST INDICATION IN U.S./EUROPE (EST 2026)

➤ PAYMENTS UP TO USD 14M FOR SECOND INDICATIONS IN CHINA, U.S. AND EUROPE

➤ ROYALTIES AND MILESTONES ON SALES IN ALL MARKETS

Q3 / Q4 NEWS ON CEVIRA:

- November 2020: First patient dosed in Phase 3 study in China
- October 2020: New EP 2983780 Patent in Europe covering the commercial Cevira device in Europe until 2034
- July 2020: Asieris received China NMPA's approval to start global Phase 3 clinical trial for APL-1702 (Cevira)

Our Mission: Delivering transformative solutions to improve the lives of bladder cancer patients



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Photocure's four step strategy will deliver our mission



Photocure's global commercial bladder cancer platform will be the foundation for transformative deals and value growth

Ambition of worldwide revenues in range of **NOK 1 Billion** in 2023
with approximate **40% EBITDA** margin

Investment Highlights



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- Photocure has established a position as an innovation leader in the bladder cancer treatment market
- Our Hexvix[®]/Cysview[®] product is a best-in-class solution for the detection, staging, and long-term management of bladder cancer
- Treatment guidelines and reimbursement support our market penetration efforts – demonstrated commercial execution
- Significant upside potential with only ~5% U.S. market share today, recent re-acquisition of Hexvix rights in Europe, and ROW partnering opportunities
- Strategy to grow organically and inorganically with plans to acquire new products, technologies, or businesses to build our bladder cancer franchise

Leading change in bladder cancer

Q&A

