

PHOTOCURE ASA

DNB NORDIC HEALTHCARE
CONFERENCE

14 DECEMBER 2017

Ambaw Bellete
President, Photocure Inc. and Head, US Cancer Commercial Operations

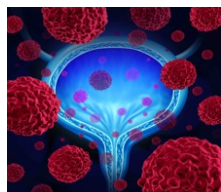


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PHOTOCURE – INVESTMENT HIGHLIGHTS



Commercial-stage company focused on Urology

- **Hexvix®/Cysview® for improved detection and management of bladder cancer**
 - Improved detection, reduced disease recurrence and progression rates with cost benefits
 - ~USD 30M global in market sales (LTM); EBITDA ~USD 2.4 million (LTM)
- **Specialist commercial and medical team established in US and Nordic region**
 - Partners in other high value territories: Ipsen (EU), Juno Pharmaceuticals (Australia/New Zealand), BioSynt Pharma (Canada)



Value building opportunities anticipated in next 12 – 24 months

- **Large untapped potential for Hexvix/Cysview in existing and new market segments/territories**
 - New positive clinical data in Flex scope/surveillance use with potential label extension in the US
 - New positive reimbursement landscape in US market
- **Exploring expansion of Urology portfolio to leverage commercial infrastructure**

THE CURRENT STATE OF BLADDER CANCER



Bladder cancer is 5TH most common cancer in the EU / 4th most common cancer (males) in the US

- Most expensive cancer : \$96 - \$187k / patient¹
- Accounts for \$3.7 billion in direct medical costs/year²
- > 200,000 new patients globally each year³
- 76,960 new US cases in 2016, 16,390 deaths in US in 2016³
- Lifetime risk of developing bladder cancer (men - 1:26; women - 1:84)³

Regular ongoing surveillance required

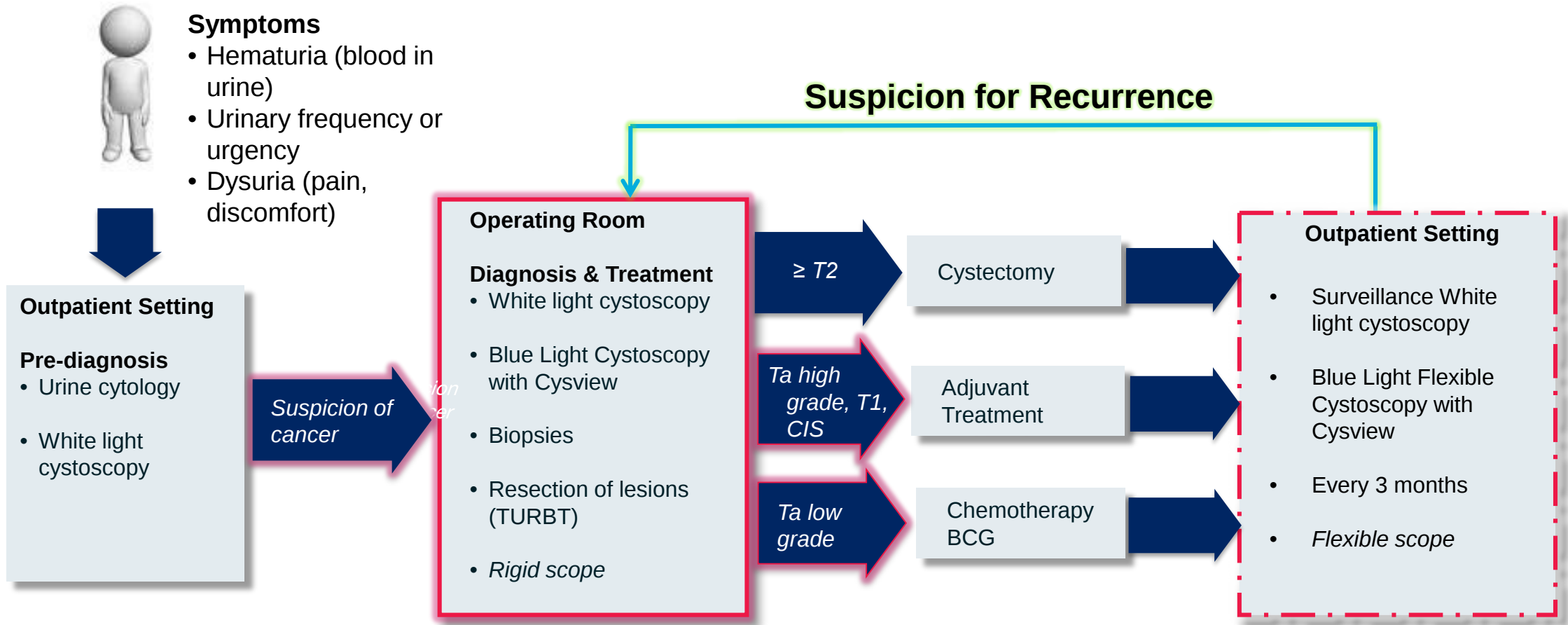
- 10% – 30% progression rate
- Diagnosed patients recommended to have follow-up cystoscopies every 3 months during first 24 months of diagnosis

Initial treatment by the numbers

- ~ 565k surgical procedures (TURBTs⁴) annually US/EU
- ~ 2.2M cystoscopies for surveillance annually US/EU

1. Scand J Urol Nephrol 2002; 36:344-7; 2. The health economics of bladder cancer: a comprehensive review of the published literature. Botteman MF et al. Pharmacoeconomics 2003;21 (8), 1315-1330 3.American Cancer Society. Bladder Cancer. 2016 4.trans-urethral resection of bladder tumors

BLADDER CANCER – THE PATIENT EXPERIENCE: SYMPTOMS, DIAGNOSIS, SURVEILLANCE & FOLLOW-UP



IMPROVING BLADDER CANCER MANAGEMENT

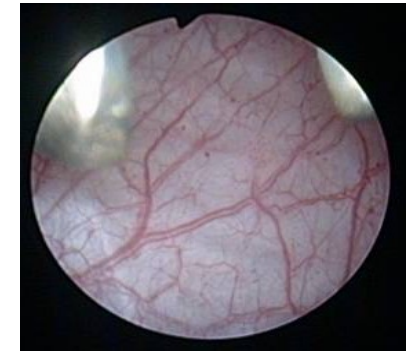
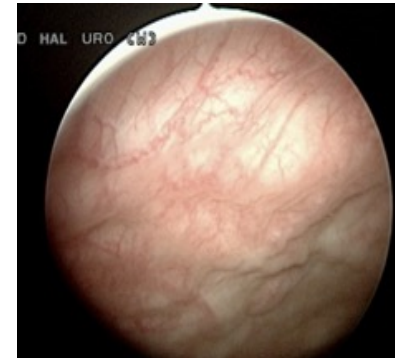
BLC with Hexvix (EU) / Cysview (US) for improved detection and management of bladder cancer

- Hexvix/Cysview is a colorless contrast solution that is used with a blue-light enabled cystoscope
- First approved drug-device procedure; launched in US in 2012
- Recommended use in 50-70% of TURBTs (bladder cancer resection procedures); included in numerous national / international clinical guidelines including AUA & EU Guidelines
- Improved tumor detection significantly reduces recurrence of bladder cancer after 9 and 12 months
- Resulting trend in reduction of progression to muscle invasive disease thereby reducing number of patients needing complete removal of bladder.
- Currently approved in operating room setting with rigid scope (US); approved for operating room and clinic / office setting in other markets

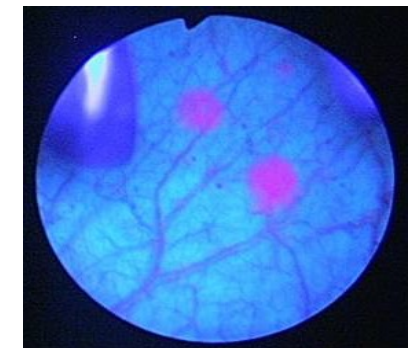
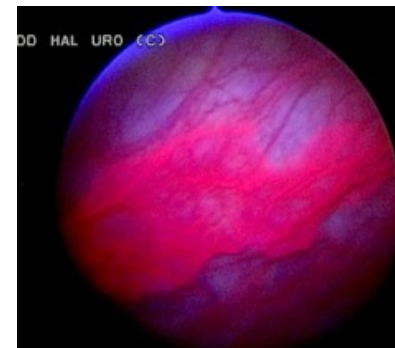
Utilizes the body's own biology to detect malignant cells

- Hexvix/Cysview contains precursors which are converted inside the cell to form an endogenous photoactive entity (PpIX)
- The solution is administered into the bladder directly and accumulates in cancerous cells, which then fluoresce red when blue-light is shone upon them

View of Bladder with use of WLC



Same view using BLC with Hexvix/Cysview



HEXVIX/CYSVIEW

A GLOBAL SPECIALTY BRAND

Increased Sales and Blue Light Cystoscopes

Sales revenues in 2016 increased YoY 11% to NOK 136M. YTD Q3 revenue increase YoY 10% to NOK 110M

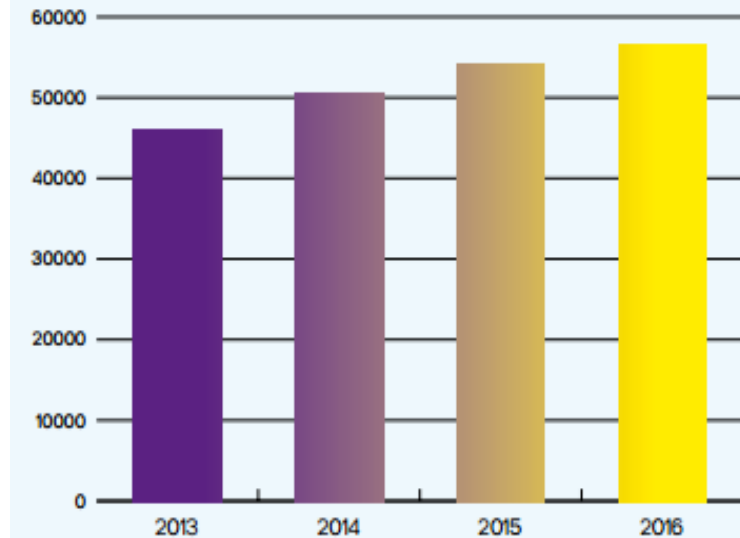
Sales revenues comprise:

- Own sales of Hexvix in the Nordic region
- Own sales of Cysview in the US
- Income from sales and royalties from license partners

In-market unit sales increased 4% YTD Q3. US increase 35%

Increased installed base of Blue Light Cystoscopes in US from 83 (YE 2016) to 96 (Q3)

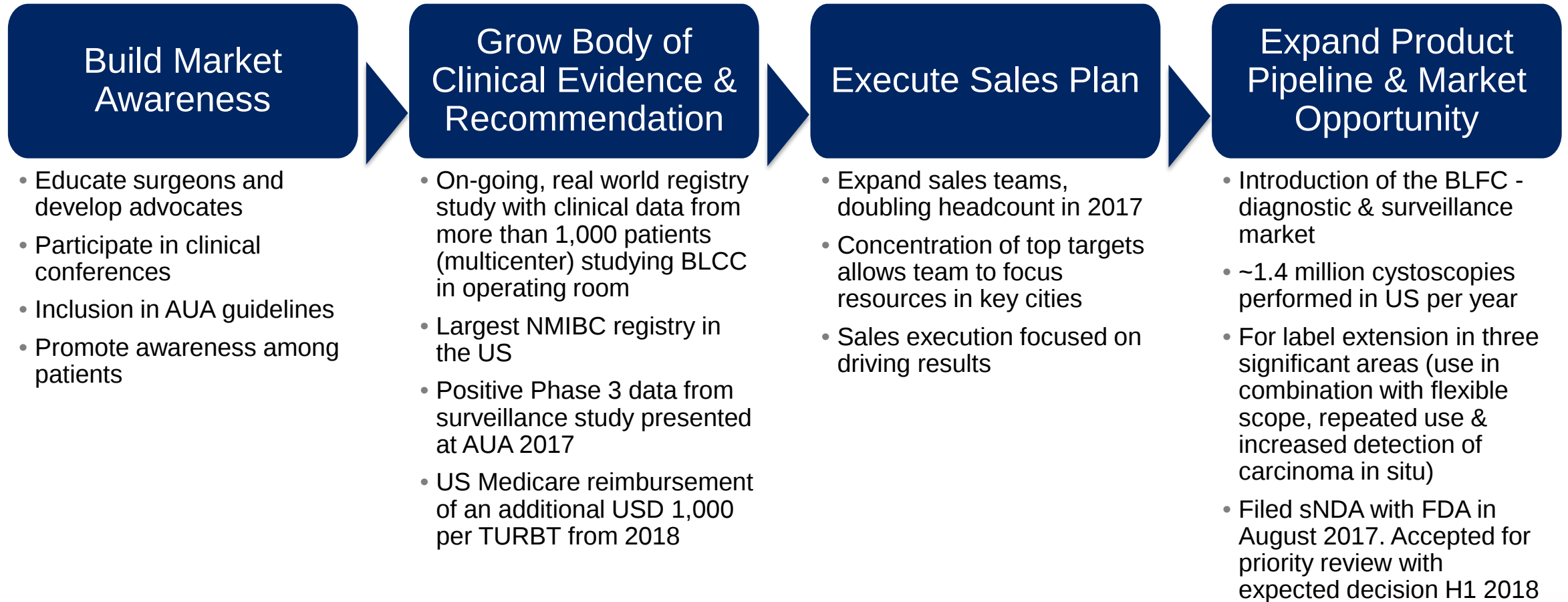
In-Market Unit Sales



- Full year in-market unit sales increased 5% in 2016, driven by growth of 21% in US
- 2016 in-market sales totaled NOK 241M compared to NOK 214M in 2015

CYSVIEW US

DRIVING ACCELERATED GROWTH



BUILDING AWARENESS: INCLUSION IN NATIONAL GUIDELINES

Transforming Clinical Practice

- US Guidelines: Use of Blue Light Cystoscopy with Hexvix/Cysview receives *highest level of recommendation* in the new AUA/SUO bladder cancer guideline
 - Recommended based on the large body of evidence supporting both increased detection and reduced recurrence of non-muscle invasive bladder cancer
- Included in European and National Guidelines in several EU countries
 - Strong recommendation recently received within French National Guidelines for Blue Light Cystoscopy with Hexvix
 - EAU altered guidelines to include the use of Hexvix as a preferential diagnosis procedure
 - NICE recommended the use of cystoscopies and that photodynamic diagnosis should be offered to patients
- Recommended use in 50-70% of TURBT procedures¹

¹) Babjuk et al., Guidelines on non-muscle-invasive bladder cancer (Ta, T1 and CIS). EAU, 2014.

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NON-MUSCLE INVASIVE BLADDER CANCER
[Download the unabridged version of this guideline \[pdf\]](#)
[Download Non-Muscle Invasive Bladder Cancer Treatment Algorithm \[pdf\]](#)

DIAGNOSIS AND TREATMENT OF NON-MUSCLE INVASIVE BLADDER CANCER: AUA/SUO GUIDELINE

Sam S. Chang, MD, MBA; Stephen A. Boorjian, MD; R. Daneshmand, MD; Badrinath R. Konety, MD, FACS, MChad R. Ritch, MD, MBA; John D. Seigne, MD; Eila Cur M. McKiernan, MD

Purpose
The survival rate for the majority of patients with non-favorable; however, the rates of recurrence and prog (MIBC) are important surrogate endpoints for overall

EAU GUIDELINES ON NON-MUSCLE INVASIVE (Ta, T1, CIS) BLADDER CANCER
(Limited text update March 2016)
M. Babjuk (Chair), A. Böhle, M. Burger, E. Compérat, E. Kaasinen, J. Palou, B.W.G. van Rhijn, M. Rouprêt, S. Shariat, R. Sylvester, R. Zigeuner
Guidelines Associates: O. Capoun, D. Cohen, V. Hernández, V. Soukup
Eur Urol 2011 Apr;59(4):584-94
Eur Urol 2013 Oct;64(4):639-53

Introduction
The EAU Working Group has published guidelines on Non-muscle-invasive bladder cancer (NMIBC). It comprises Ta and T1 tumours as well as carcinoma in situ (CIS).

Staging and classification systems
The TNM Classification of Malignant Tumours, 7th Edn., 2009 will apply (Table 1).

T - Primary tumour	
Tx	Primary tumour cannot be assessed
T0	No evidence of primary tumour



GROW BODY OF CLINICAL EVIDENCE: INCREASING EXPOSURE IN MEDICAL COMMUNITY

Increased Exposure to Urologists

Continued Positive Data Flow Fuels Forward Momentum

- New publications in *Bladder Cancer* show Blue Light Cystoscopy (BLC) with Hexvix/Cysview significantly improves long term outcomes
 - Significantly prolongs time to progression of bladder cancer (Kamat et al, April)**
 - Significantly reduces progression of bladder cancer (Gakis et al, August)**
- Publication in *The Journal of Urology* shows BLC with Hexvix/Cysview has no increase in adverse events when a one-off procedure to compared to repeats
- A «Real-life experience» study performed at single center in UK enrolled 808 bladder cancer patients published in *World Journal of Urology*
 - BLC with Hexvix showed reduced disease recurrence rate at 3 years compared to standard WLC resection (39.0% vs 53.3%; $p=0.02$)**
- New study in *World Journal of Urology* shows that BLC with Hexvix/Cysview significantly improves detection of NMIBC

On-going real world registry study provides clinical evidence

- Data from more than 800 patients in the US
- US Bladder Cancer Registry Study including results from 533 patients on 641 BLC with Cysview procedures were presented at the recent International Congress of Urology (SIU)

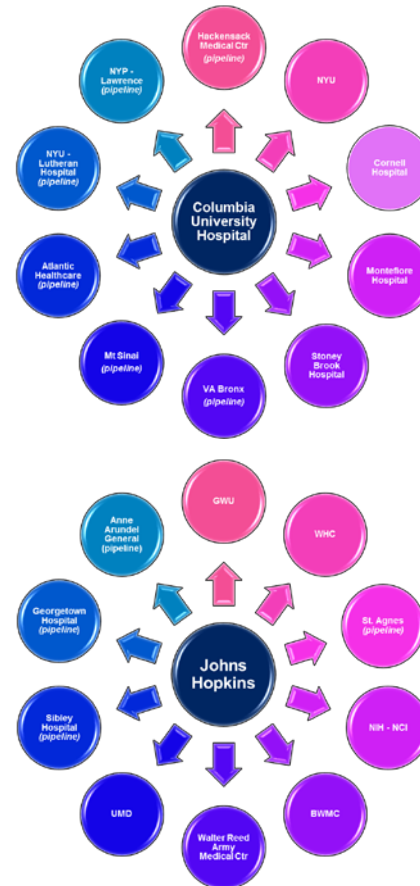


EXECUTE SALES PLAN: MAXIMIZING SALES EFFICIENCY TARGETING TOP 25 MARKETS

Top 25 markets – TURBT rank

Metropolitan statistical area	Totals (inpatient & outpatient TURBT procedures*): Total
New York, Newark, Jersey	21,284
Chicago, Naperville, Elgin	9,649
Philadelphia, Camden, Wilmington	6,256
Los Angeles, Long Beach, Anaheim	5,994
Miami, Fort Lauderdale, West Palm Beach	5,436
Tampa, St. Petersburg, Clearwater	5,010
Boston, Cambridge, Newton	4,768
Detroit, Warren, Dearborn	4,054
Phoenix, Mesa, Scottsdale	3,998
Baltimore, Columbia, Towson	2,862
Houston, The Woodlands, Sugar Land	2,763
Washington, Arlington, Alexandria	2,700
St. Louis	2,535
Orlando, Kissimmee, Sanford	2,339
Atlanta, Sandy Springs, Roswell	2,136
Dallas, Fort Worth, Arlington	2,076
Cleveland, Elyria	1,937
Cincinnati	1,923
Cape Coral, Fort Myers	1,712
Pittsburgh	1,685
North Port, Sarasota, Bradenton	1,672
Jacksonville	1,671
Providence, Warwick	1,613
Minneapolis, St. Paul, Bloomington	1,544
Nashville, Davidson, Murfreesboro, Franklin	1,535

Example anchor accounts

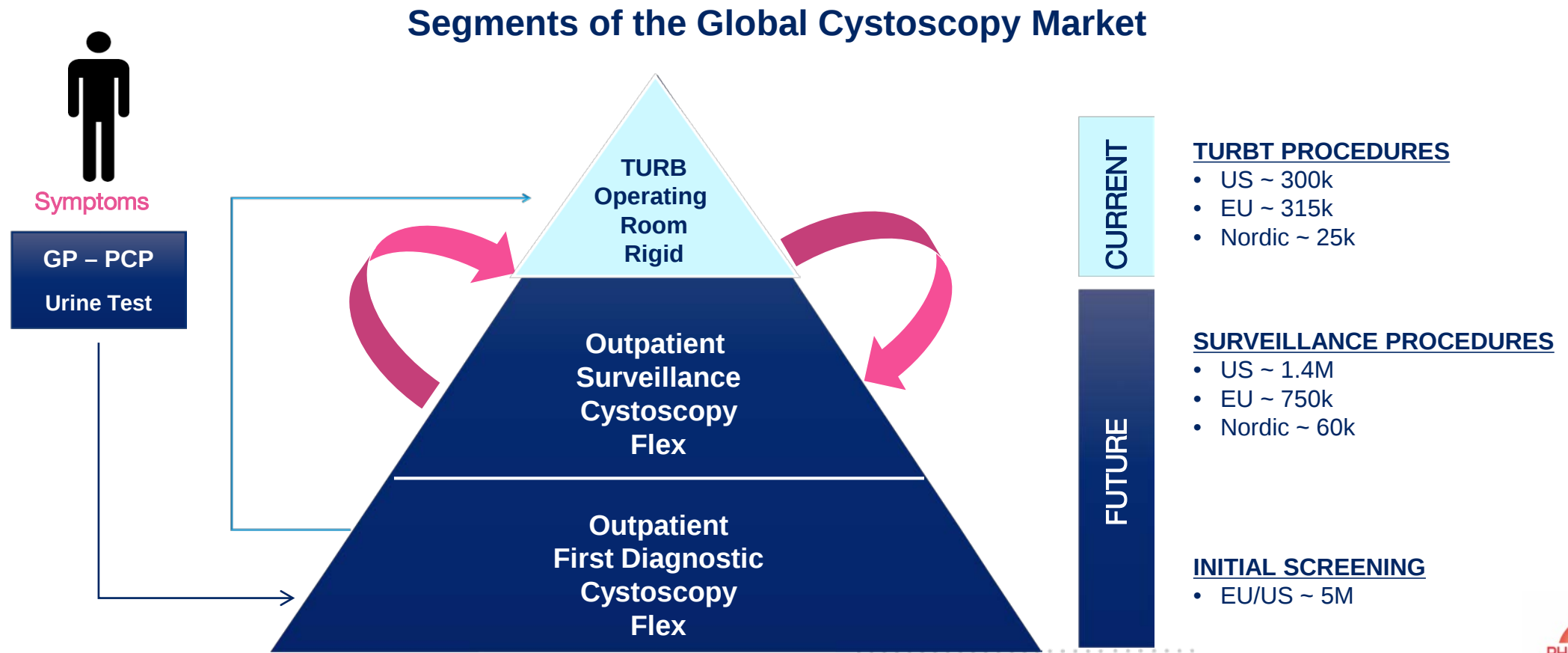


Comments

- Focus efforts to establish and build Cysview business in top 25 TURBT markets
- 400 major hospitals represents ~40% of total US TURBT market
- Establish well known academic hospitals as anchor and referral accounts
- Expand by targeting and establishing new accounts in reachable proximity to the anchor accounts
- Utilize marketing and sales resources in a focused and efficient way

EXPANSION INTO LARGER SEGMENTS: MARKET OPPORTUNITY IN THE SURVEILLANCE SEGMENT

- Expansion with Blue Light Flexible Cystoscopy with Cysview
- For office settings (surveillance and first diagnostic) that utilize flexible cystoscopes



EXPANSION INTO LARGER SEGMENTS: PHASE 3 CLINICAL TRIAL RESULTS REPORTED AT AUA 2017

Overview

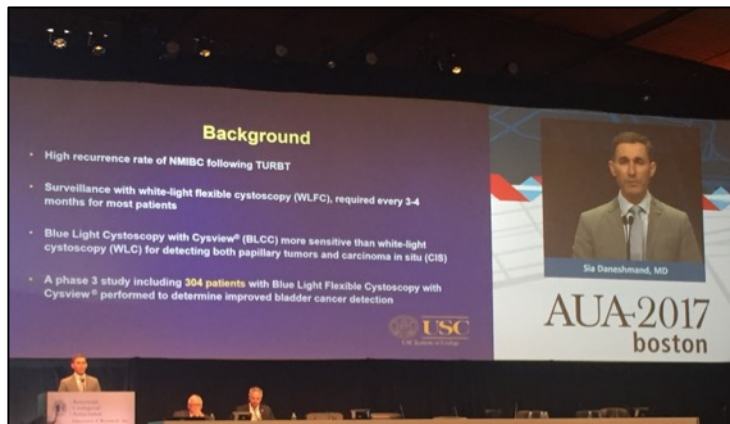
- **Compare use of Blue Light Cystoscopy with Cysview and white light** using the blue light enabled Flexible cystoscope device (KARL STORZ)
- 100mg of Cysview as intravesical solution instilled in the bladder, with 1 hour wait prior to Cystoscopy

Endpoints

- **Primary endpoint** - the rate at which malignancy is detected with Cysview compared to white light using flexible scopes
- **Secondary endpoint (1)** - proportion of patients with adverse events from the procedure after repeated administration
- **Secondary endpoint (2)** - # of patients with one or more CIS (Carcinoma in situ; flat, aggressive lesions) lesions that are detected with Cysview when white light detects none

Conclusion

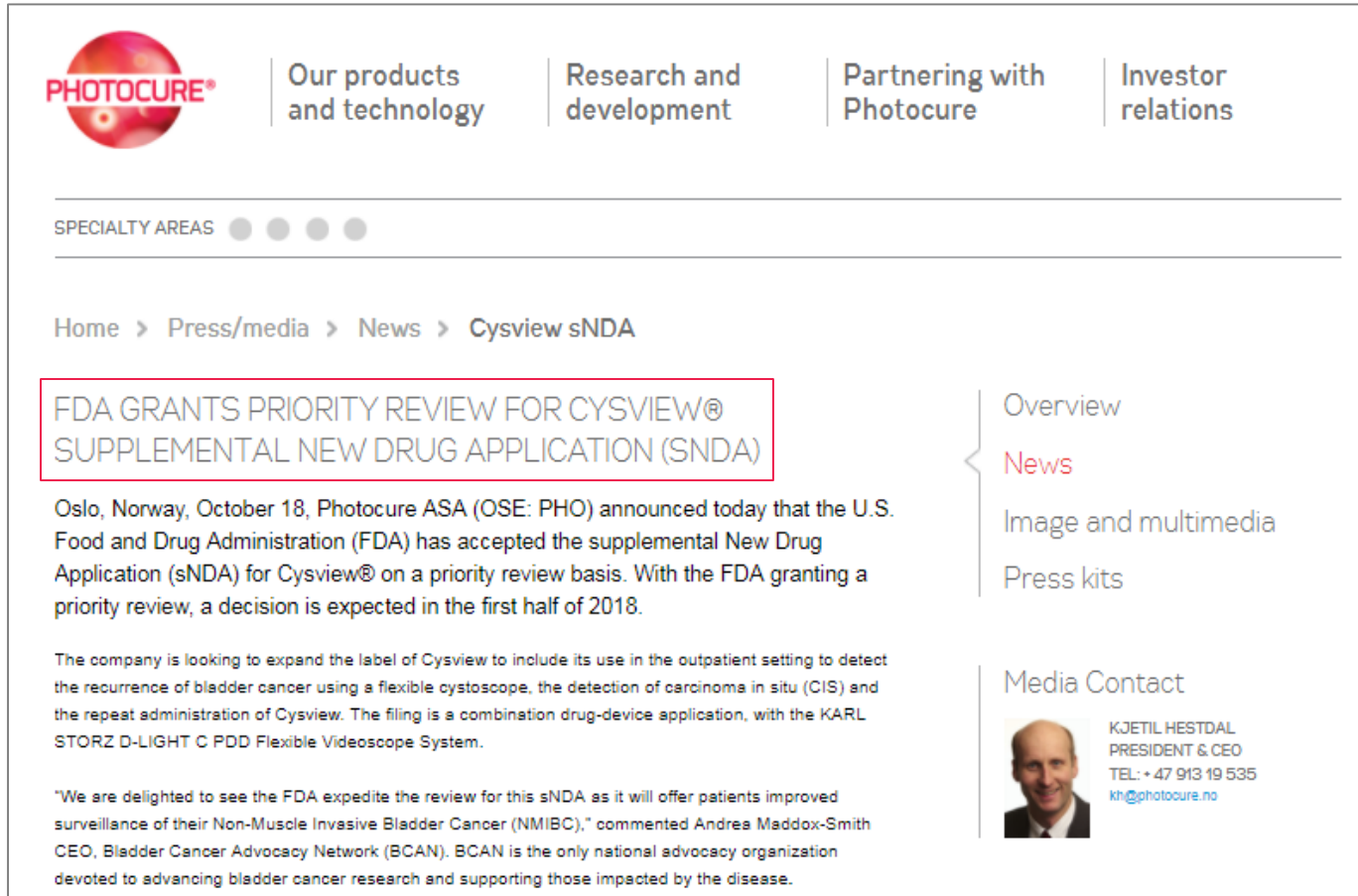
- **BLFCC** significantly improves the detection of patients with recurrence of bladder cancer (**20.6%**, $p<0.0001$)
- **BLCC** significantly improves the detection of patients who recurred with CIS (**34.6%**, $p<0.0001$)
- Repeat use of **BLCC** improves tumor detection in **46.2%** of the patients and is **safe**
- **Patients** found it **worthwhile** to undergo **BLFCC (92.7%)** and **BLCC (87.0%)** and would recommend it to others



BLFCC should be used for patients in surveillance of their bladder cancer recurrence and for management in the operating room



EXPANSION INTO LARGER SEGMENTS: SUPPLEMENTAL NEW DRUG APPLICATION – PRIORITY REVIEW



The screenshot shows the Photocure website's news section. At the top is the Photocure logo and navigation links: 'Our products and technology', 'Research and development', 'Partnering with Photocure', and 'Investor relations'. Below these are 'SPECIALTY AREAS' and a breadcrumb trail: 'Home > Press/media > News > Cysview sNDA'. The main headline is 'FDA GRANTS PRIORITY REVIEW FOR CYSVIEW® SUPPLEMENTAL NEW DRUG APPLICATION (SNDA)'. The text below the headline states: 'Oslo, Norway, October 18, Photocure ASA (OSE: PHO) announced today that the U.S. Food and Drug Administration (FDA) has accepted the supplemental New Drug Application (sNDA) for Cysview® on a priority review basis. With the FDA granting a priority review, a decision is expected in the first half of 2018.' A sidebar on the right contains links for 'Overview', 'News' (highlighted), 'Image and multimedia', and 'Press kits'. At the bottom of the sidebar is a 'Media Contact' section featuring a photo of Kjetil Hestdal, President & CEO, with his contact information: 'TEL: + 47 913 19 535' and 'kh@photocure.no'. The main text continues: 'The company is looking to expand the label of Cysview to include its use in the outpatient setting to detect the recurrence of bladder cancer using a flexible cystoscope, the detection of carcinoma in situ (CIS) and the repeat administration of Cysview. The filing is a combination drug-device application, with the KARL STORZ D-LIGHT C PDD Flexible Videoscope System.' A quote from Andrea Maddox-Smith, CEO of BCAN, follows: 'We are delighted to see the FDA expedite the review for this sNDA as it will offer patients improved surveillance of their Non-Muscle Invasive Bladder Cancer (NMIBC),' commented Andrea Maddox-Smith CEO, Bladder Cancer Advocacy Network (BCAN). BCAN is the only national advocacy organization devoted to advancing bladder cancer research and supporting those impacted by the disease.'

- Expanded indications to include combination of Cysview with KARL STORZ Flexible Videoscope System in addition to current Rigid Scope System targeting surveillance cystoscopies of patients diagnosed NMIBC
 - *Of the total 1.4 million cystoscopies performed in the US each year approximately 600 000 estimated to be performed in surveillance of patients with high and medium risk NMIBC*
- The sNDA will also expand the indication in the current rigid setting (TURBT) by obtaining expanded indication to involve improved detection of CIS¹ in bladder cancer patients as well as repeated use of Cysview

US MEDICARE REIMBURSEMENT OF AN ADDITIONAL USD 1,000 PER TURBT FROM 2018*

	Medicare (~55% of TURBT)	Private payer (~45% of TURBT)
Cystoscopy	• Procedure fee for cystoscopy • Cysview paid at ASP** +6% • No change from 2017	• Procedure fee for cystoscopy • Cysview paid at contracted rate (ASP** +6 to 15%) • No change from 2017
TURBT	• Hospital Outpatient Depts. will receive an additional \$1,000 to cover the complexity of using Cysview and Blue Light Cystoscopy procedure for the following codes: 52204, 52214 & 52224 • Bundled into ambulatory payment classification (APC – varies by TURBT type)¹ for the higher procedure codes of 52234, 52235 and 52240	• Procedure fee for TURBT – varies by type • Cysview paid at (Average Selling Price -ASP +6 to 15%) • No change from 2017

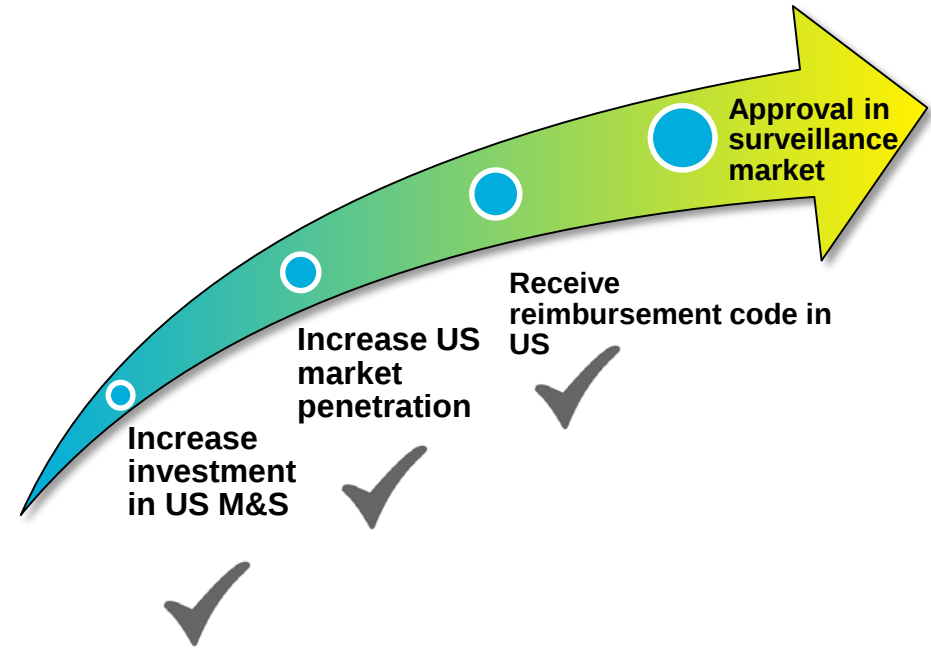
New Medicare reimbursement accounts for ~50% of TURBT Medicare market



CYSVIEW US

CONTINUED STRONG MOMENTUM

- Photocure own sales revenue in the US in 3Q increased 45% YoY
 - Driven by YoY in-market volume growth of 39% in third quarter
 - 6th quarter with QoQ sales revenue growth in the US, despite seasonality
- Permanent Blue Light Cystoscope placements of 96 at the end of quarter, increase of 13 since end of 2016
- US strategic investment plan is on track and we have doubled our sales organization, increased medical headcount and targeted marketing investments

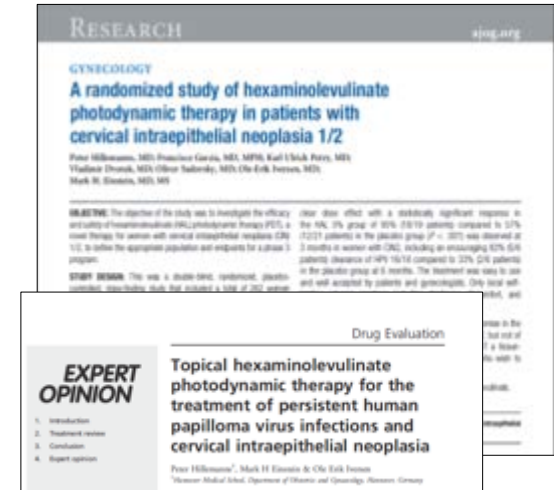


Maximizing the US Cysview opportunity is essential to Photocure's strategy to create a Specialty Pharmaceutical Company in Urology

CEVIRA & VISONAC

PHASE 3 READY PRODUCTS WITH SIGNIFICANT SALES POTENTIAL

- Cevira - Breakthrough single use and fully integrated drug-device technology to satisfy high need for novel non-surgical therapies to treat global epidemic of HPV/HSIL populations
- Visonac – Novel topical non-antibiotic/non-isotretinoin treatment to satisfy high unmet medical need among patients with inflammatory, severe acne (IGA 4)
- Cevira and Visonac both phase 3 ready with Special Protocol Agreement on phase 3 program with FDA
- Cevira and Visonac both addressing large patient populations with significant unmet medical needs
- After a non-conclusive comprehensive partnering process, PHO continues to review of possible strategic alternatives for Cevira and Visonac



KEY FINANCIALS – YTD Q3 2017

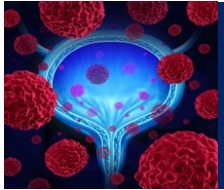


Income Statement - Segments			
<i>MNOK</i>	<u>YTD '17</u>	<u>YTD '16</u>	<u>Change</u>
<u>Commercial Franchise</u>			
Nordic revenues	30.4	29.4	3 %
US revenues	32.3	22.4	44 %
Partner revenues	47.0	47.5	-1 %
Hexvix / Cysview	109.6	99.4	10 %
Other revenues	1.9	6.2	-69 %
Total revenues	111.5	105.5	6 %
EBITDA recurring	9.4	19.3	
<u>Development Portfolio</u>			
EBITDA recurring	-27.7	-27.0	
<u>Total</u>			
EBITDA recurring	-18.3	-7.7	
One-Off items	-4.0	0.0	
EBITDA	-22.3	-7.7	

- Q3 Hexvix/Cysview revenues driven by US
 - US sales +44%. Installed base of BLC at 96 (YE 2016: 83)
 - Nordic revenues improved from a slow start of the year. 3% increase YTD. Previous sales decline was due to temporary loss of procedures relating to reorganization of clinics in Denmark, and FX
 - Revenues from Partner at level with last year. Sales growth in Germany and Austria offset by declines in other countries
 - Blue Light Flexible Cystoscopy gaining foothold in Nordic regions
 - Operating expenses increased due to investments in US market and preparation for expansion into surveillance segment
 - Ending cash balance Q3: NOK 123M



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