

# PHOTOCURE ASA

## RESULTS FOR FOURTH QUARTER AND FULL YEAR 2018

27 February 2019

Daniel Schneider, President and CEO  
Erik Dahl, CFO



THE  
BLADDER CANCER  
COMPANY™

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# DELIVERING ON KEY 2018 OBJECTIVES

## Significant growth of Cysview® in US TURBT market

- Q4 revenue growth in US\$ 76%, full year 53%, driven by in-market volume increase in Q4 of 69%, full year 45%
- 51% growth YOY in installed blue light enabled cystoscopes in market to 157 by end of year, including 8 Flex cystoscopes
- Improved reimbursement has positively impacted sales development including new account install base

## Launch Cysview® in US flexible cystoscopy surveillance market

- Our launch priority is focused on the accounts that participated in the BL Flex trial, current existing targeted accounts and top large Urology groups in the US
- Our pipeline of potential new accounts continues to grow driven by customer and patient demand

## Increase Hexvix® / Cysview® global in-market unit sales

- Total Hexvix/Cysview revenue increased 28% YOY to NOK 46.3 million in Q4, highest ever. Full year growth of 19% (proforma)
- Total in-market unit sales increased 11% in Q4. Full year increase of 5% driven by US

# STRATEGIC FOCUS ON TRANSFORMING BLADDER CANCER DETECTION AND MANAGEMENT



Profitable  
commercial franchise

Hexvix®/Cysview® ~\$35M global in-market sales\* (FY'18)  
Over 500k patients treated with Hexvix® / Cysview® worldwide



Strong  
competitive position

Unique and complex drug-device procedure  
Leading regulatory, manufacturing & commercial expertise



Significant  
growth prospects

Grow in existing markets like the US & expand into new regions  
FLEX label extension accessing a larger market opportunity



Leverage  
commercial operations

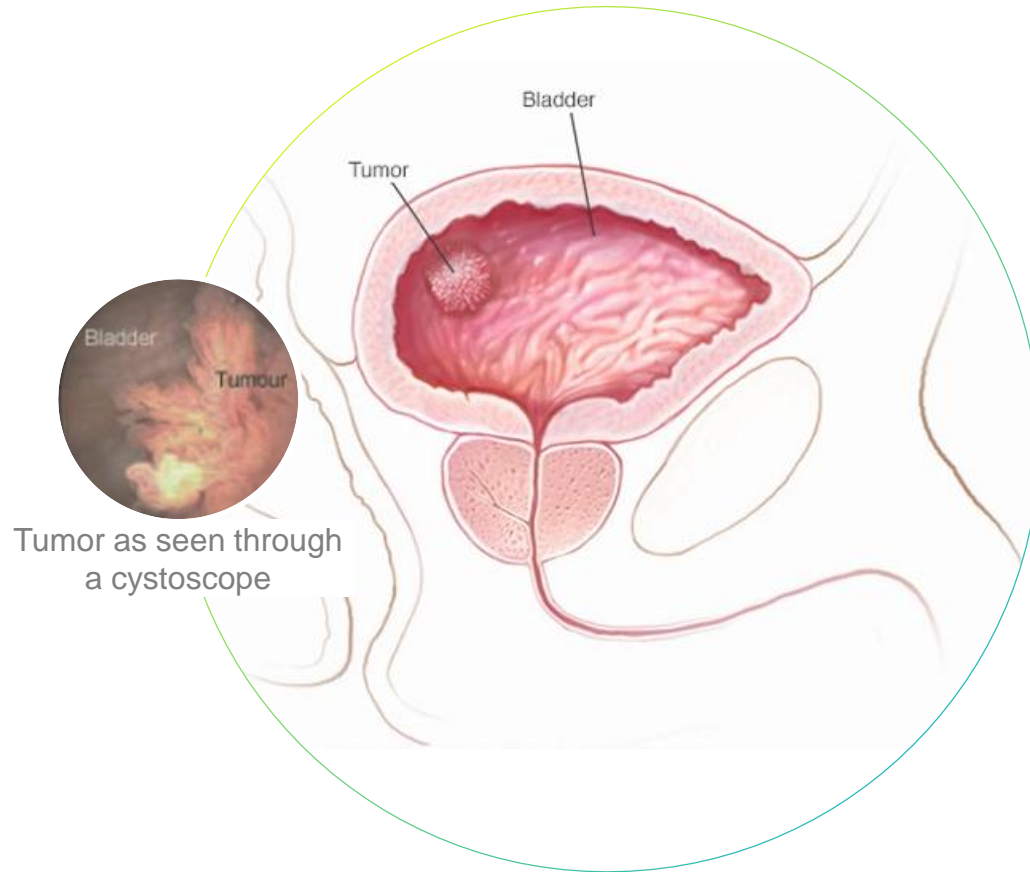
Scalable for partnerships and in-licensing opportunities

\* Total In Market Sales including US, Nordic and Partners

# *Hexvix/Cysview Update*



# NON-MUSCLE INVASIVE BLADDER CANCER IS ONE OF THE MOST COMMON CANCERS WITH SIGNIFICANT RECURRENCE RATE AND HIGH DISEASE BURDEN



**~650K**  
surgical procedures  
annually in USA and EU

**~2.2M**  
surveillance cystoscopies  
annually in USA and EU

**50%**  
disease recurrence

**10% – 30%**  
disease progression

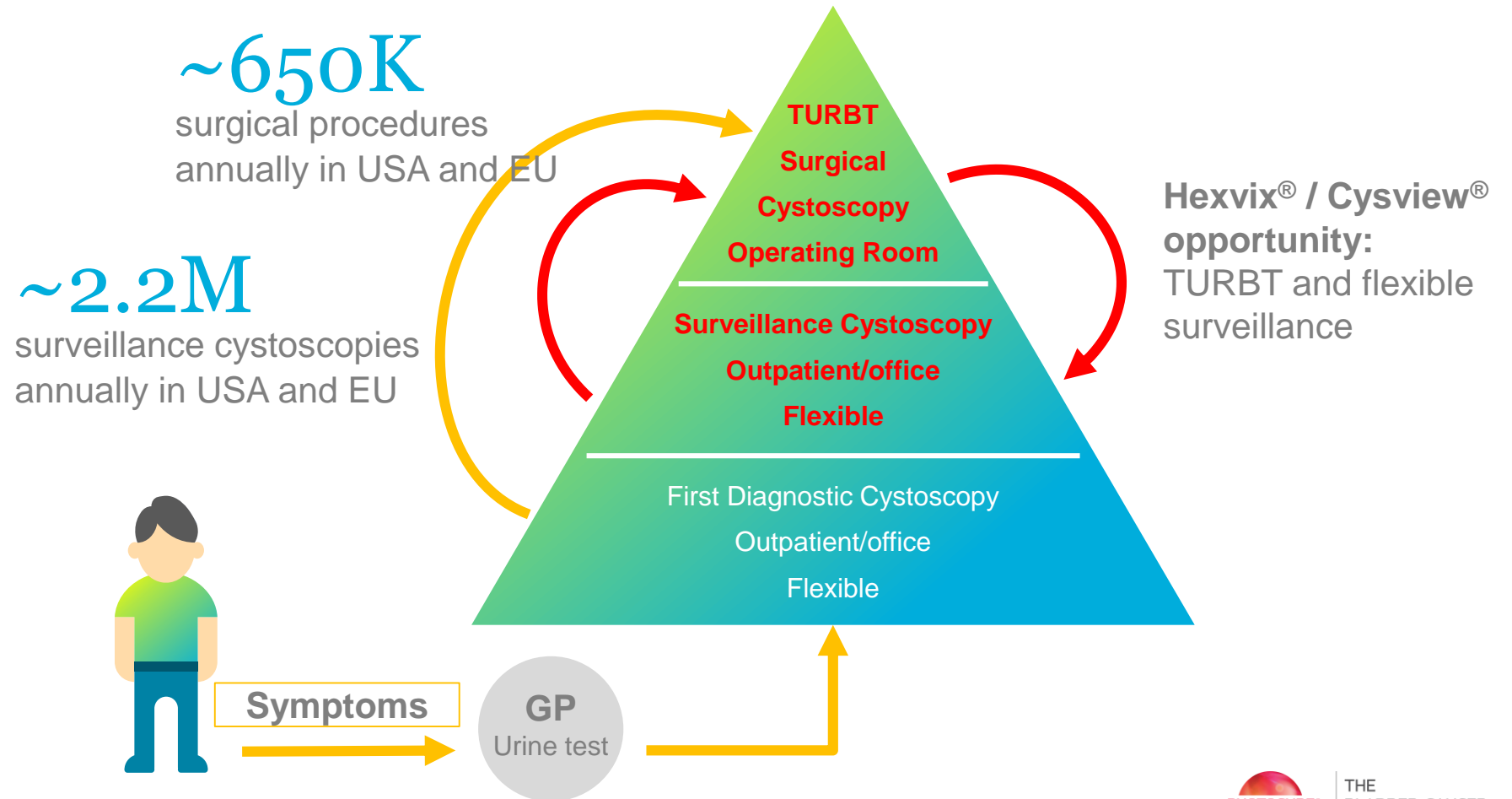
**\$3.7 Billion**  
in direct medical costs/year<sup>1</sup>

Picture: Mayo Clinic; Researchgate.net

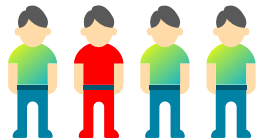
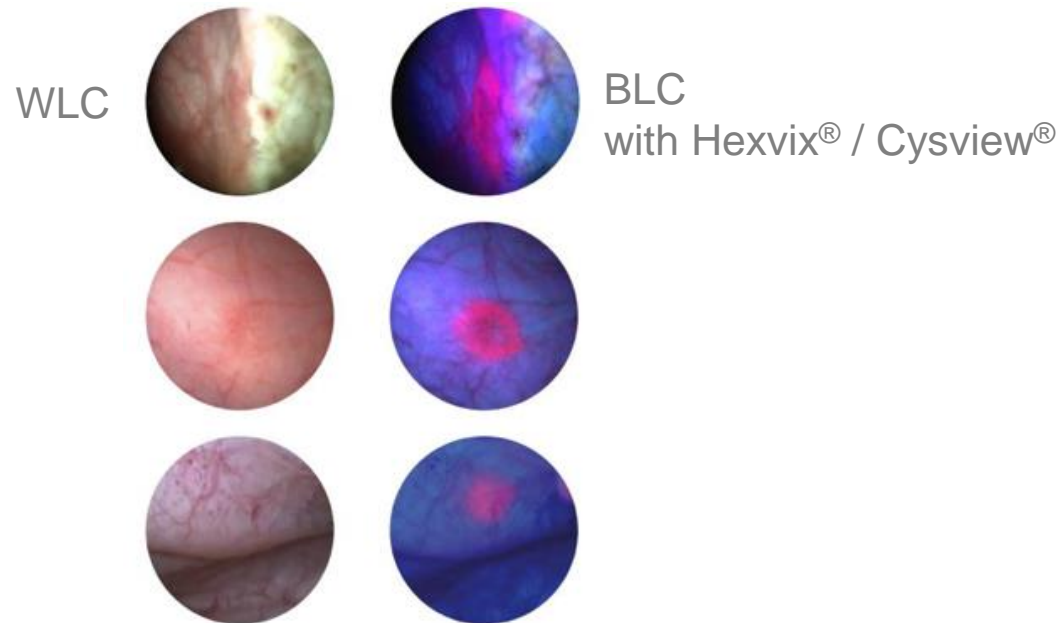
1. Direct medical costs in USA in 2001: The health economics of bladder cancer: a comprehensive review of the published literature. Botteman MF et al. Pharmacoeconomics 2003;21 (8), 1315-1330

# EXPANDING INTO FLEX IS ONE OF OUR BIG NEXT STEPS

The flexible surveillance market is approximately 3X bigger than the rigid TURBT market



# HEXVIX® / CYSVIEW® IS A TRANSFORMATIVE SOLUTION TO IMPROVE THE LIVES OF PATIENTS WITH BLADDER CANCER



**Additional tumors found  
in 1 out of 4 patients<sup>1</sup>**

<sup>1</sup> Burder et al, Eur. Urol. 2013  
WLC: White Light Cystoscopy; BLC: Blue Light Cystoscopy™ + Cysview®

**Key feature**  
Better visual contrast  
between benign  
and malignant cells

**Key benefits**  
Improve diagnostic  
accuracy  
Achieve optimal  
surgical results



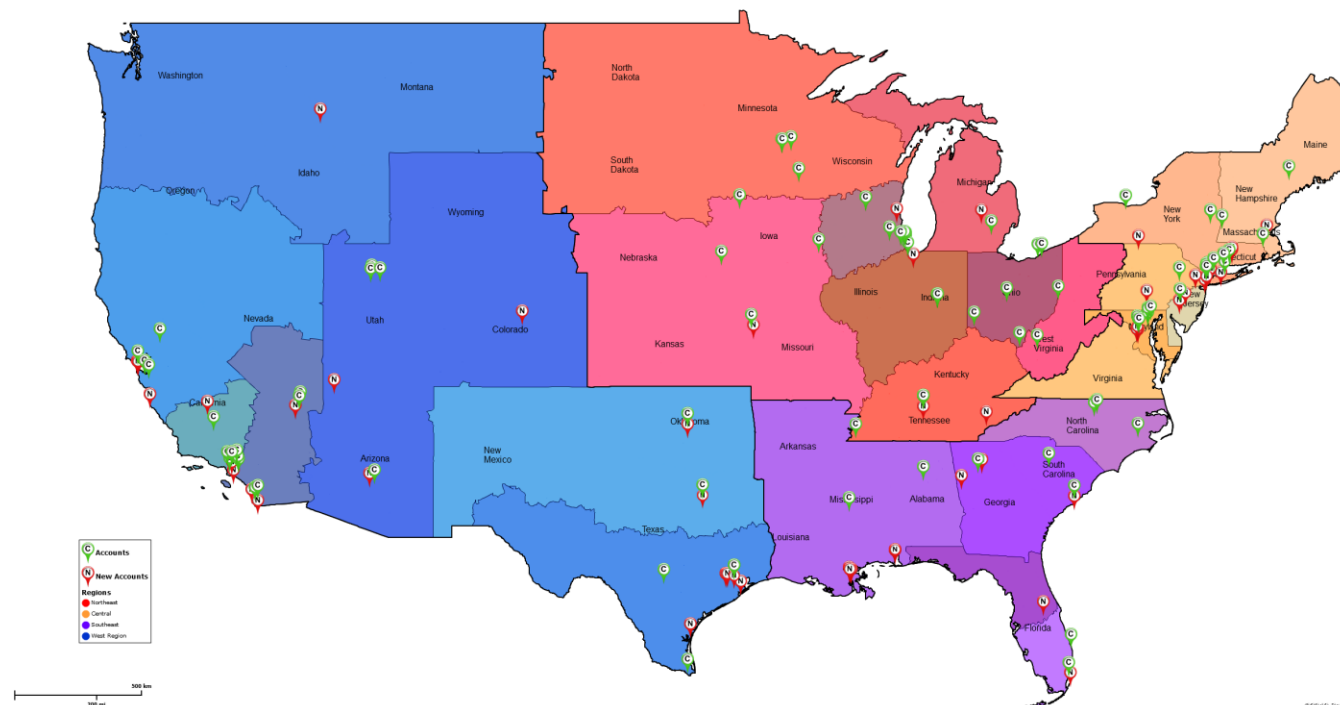
Significant reduction of disease recurrence  
Reduction in disease progression  
Potential for reduction in cystectomies  
Improved and cost-effective health outcomes



# 50% INCREASE IN CUSTOMER FACING ROLES IN 2019

## 75% MSA COVERAGE

Commercial Role	2016	2017	2018	2019
Surgical Sales Executives	11	15	21	27
Corp Account Mgrs. (LUGPA and IDHN)	0	0	0	4
Total FTEs	11	15	21	31
Total Account Coverage	275	375	525	750+



# INCREASING PATIENT AWARENESS & DEMAND

## NOV/DEC 2018 MEDIA PROGRAMS: HCP & PATIENT

.....www.auanet.org banners: July-Dec

USA Today Nov 29

**APPROVED FOR SURVEILLANCE AND TUMOR DETECTION**

**CYSTOSCOPY WITH CYSVIEW<sup>®</sup>**  
Hexaminelavinate HCl

**Important risk & safety information**  
Cysview is not a replacement for random bladder biopsies or other procedures used in the detection of bladder cancer.

**Journal of Urology | Guidelines | Annual Meeting**

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**Advancing Urology**

AUA promotes the highest standards of urological clinical care through education, research and the formulation of health care policy.

**Inside Tract**

**AUA Investigator 2018 Issue 1: Now Available!**

Check out the latest issue of AUA Investigator, a digital newsletter featuring the latest news and information impacting the urologic research community.

**Read the Issue**

**Free Webcasts from AUA2018 – Earn FREE CME!**

If you didn't make it to San Francisco for AUA2018, you can access more than a dozen FREE webcasts from the 2018 Annual Meeting! These webcasts offer FREE CME and include videos on immuno-oncology; operative bladder; prostate cancer; and renal cell carcinoma.

**Learn more**

**Physician Scientist Residency Training Award - Now Accepting Applications**

Medical students in their senior year and recent medical school graduates with a passion for urology

**Calendar of Events**

Month	Day	Event
AUG	14	AUA Castration-Resistant Prostate Cancer (CRPC) Guideline Amendment: Webinar
AUG	22	Emerging Treatment of Non-Metastatic Castration-Resistant Prostate Cancer (CRPC): Webinar
SEP	12	Androgen Axis Agents and Bone Target Therapies in Advanced Prostate Cancer: Webinar
SEP	14	Life Long Learning Prep Course: A Focused Review

**As soon as you see a rapidly rising PSA and confirm a diagnosis of non-metastatic castration-resistant prostate cancer...**

**BLUE LIGHT CYSTOSCOPY WITH CYSVIEW<sup>®</sup>**

**CYSVIEW<sup>®</sup>**  
Hexaminelavinate HCl

**Important risk & safety information**  
Cysview is not a replacement for random bladder biopsies or other procedures used in the detection of bladder cancer.

## Prostate & Urological Health

5 | FUTUREOFPERSONALHEALTH.COM

**MediaPlanet**

### This Telltale Symptom of Bladder Cancer Is Too Frequently Overlooked

Each year, 16,000 Americans die of bladder cancer and 79,000 new cases are diagnosed. Despite the number of people affected, there's little knowledge of the disease and no specific test for regular screening. Being knowledgeable of symptoms is all we have.

**Bladder cancer occurs** when the cells of the bladder lining start to grow uncontrollably. Symptoms can include increased urgency and frequent urination, as well as irritation when urinating. The most common symptom — blood in the urine, clinically known as hematuria — is often overlooked or mistaken as a symptom of a urinary tract infection or a kidney stone.

**Common concern**  
"It's a significant public health issue," says Dr. Gary D. Steinberg, chairperson for the Scientific Advisory Board for the Bladder Cancer Advocacy Network and director of Urologic Oncology at University of Chicago Medical Center. "There's a lack of awareness."

However, there has been a wealth of new clinical trials, as well as two new FDA-approved treatments for bladder cancer in the past 2-3 years — including the approval of Tecentriq and Opdivo, novel immunotherapies for bladder cancer.

"People with bladder cancer, especially celebrities, are very, very reticent to let anyone know," says Dr. Steinberg, mentioning Frank Sinatra, Hubert Humphrey and Cardinal Francis George, the former archbishop of Chicago, all had bladder cancer. "Patients don't talk about it."

**Diagnosis**  
Bladder cancer is what Dr. Steinberg describes as a "diagnosis of the disease of aging," explaining the average age of a bladder cancer patient in the United States is 73; however, bladder cancer can also occur in all age groups.

It's 3-4 times more common in men than women. Still, the disease affects women and is associated with a higher mortality rate in women than men. "Early diagnosis and detection does lead to better outcomes,"

**Patients know to get mammograms, pap smears and colonoscopies, but they don't get screened for bladder cancer.**

says Dr. Steinberg, encouraging patients and doctors to work together to understand why a patient has blood in their urine. Often, patients and doctors don't take the potential warning sign seriously. Whether hematuria is microscopic or larger, a patient should get tested with urine culture, urine cytology, CT scan and cystoscopy. Newer detection methods include using enhanced cystoscopy techniques with Cysview and Blue light cystoscopy allowing the urologist to more accurately identify, biopsy and remove the bladder tumor.

**Risk factors**  
Patients know to get mammograms, pap smears and colonoscopies but they don't get screened for bladder cancer. In part, because there's no definitive, sensitive screening test to diagnose the disease.

Knowing who's at risk may help patients and providers detect the cancer. However, all patients with blood in their urine should be tested, especially men over 50 and women after they enter menopause.

Smokers are at significant risk for developing the disease, and smoking is the greatest modifiable risk factor for bladder cancer. At least 4-5 times as often as non-smokers. Others at risk may include people who work in the rubber, petroleum or chemical industries. These jobs can expose workers to carcinogens in the workplace environment, such as petroleum products, aromatic amines and diesel exhaust.

**Kristen Castille**

**FOR MORE INFORMATION VISIT US ON CYSVIEW.COM**

**Important risk & safety information**  
Cysview is not a replacement for random bladder biopsies or other procedures used in the detection of bladder cancer. Anaphylactic shock, hypersensitivity reactions, bladder pain, cystitis, and abnormal urinalysis have been reported after administration of Cysview. The most common adverse reactions seen in clinical trials were bladder spasms, dysuria, hematuria, and bladder pain.

Cysview should not be used in patients with porphyria, gross hematuria, or with known hypersensitivity to hexaminelavinate or any derivative of hexaminelavinate. Cysview may also be used in patients with known hypersensitivity to hexaminelavinate in human or animal use, the effects on a breastfed infant, or the effects on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for Cysview and any potential adverse effects on the breastfed infant from Cysview or from the underlying medical condition. Cysview is approved for use with the KALIS STORZ D-Light C-Photodynamic Diagnostic (PDD) system. For system set up and general information for the safe use of the PDD system, please refer to the KALIS STORZ instruction manuals for each of the components.

**Prior to Cysview administration, read the Full Prescribing Information and follow the preparation and reconstitution instructions.**

**Reference: 1. Cysview (prescribing information)**  
Photocure, NJ Photocure USA, 2018.

**CYSVIEW<sup>®</sup>**  
Hexaminelavinate HCl

**Shown to outperform White Light Cystoscopy alone in detecting bladder cancer tumors\***

**CONFIDENCE AT FIRST SIGHT**

Bladder image under white light

Same image using blue light and Cysview

**PHOTOCURE<sup>®</sup>**

**THE BLADDER CANCER COMPANY<sup>™</sup>**



THE  
BLADDER CANCER  
COMPANY<sup>™</sup>

# PATIENTS WANT BLUE LIGHT CYSTOSCOPY AND CYSVIEW®

Majority stated that the availability of BLC with Cysview is a determining factor in selecting a physician and a facility for both surveillance and TURBT

Jan. 2016 n=222, Jan. 2017 n=568, Jan. 2018 n=550, Jan. 2019 n=600

Once diagnosed with bladder cancer,  
**99% of patients**  
sought out an institution that offers BLC™ with Cysview®

Diagnosed Patients Switching  
to Institutions that Offer BLC with Cysview



1. Survey of self-selected patients completed through the Bladder Cancer Advocacy Network (BCAN) sponsored by Photocure.

# CYSVIEW® TO BECOME THE NEW STANDARD OF CARE FOR THE DETECTION AND MANAGEMENT OF BLADDER CANCER IN THE USA

Supportive  
environment

Strongly recommended by national guidelines and expert panels  
New reimbursement (Jan '19) for Medicare patients



High adoption  
rate in leading sites

Established in >140 key cancer hospitals and leading institutions  
and the numbers are growing

in 74%  
NCCN centers



in 56% of  
NCI centers



in 74% of top  
25 Best Hospitals





# HEXVIX® TO BECOME THE NEW STANDARD OF CARE FOR THE DETECTION AND MANAGEMENT OF BLADDER CANCER IN EUROPE

Supportive  
environment

Strongly recommended by European and  
national guidelines as well as expert panels



DANSK UROLOGISK CANCER GRUPPE

**NICE** National Institute for  
Health and Care Excellence



 **Helsedirektoratet**



Continued growth  
in the Nordics

**25% to 70%** penetration rate

**9%** revenue growth during full year 2018

Further leverage commercial infrastructure – Combat Medical

Improve penetration  
in Rest of Europe

Well established in Germany with **30%** penetration rate

Opportunity to increase penetration in rest of Europe



# SEGMENT PERFORMANCE - PROFORMA

## FOURTH QUARTER 2018

<i>Amounts in NOK million</i>	<b>Q4 '18</b>	<b>Prof Q4 '17</b>	<b>Change</b>	<b>FY '18</b>	<b>Prof FY '17</b>	<b>Change</b>
<b>Commercial Franchise</b>						
Nordic revenue	13.5	12.9	5%	47.0	43.3	9%
US revenue	18.4	10.2	81%	63.7	42.4	50%
Partner revenue	14.4	13.2	9%	62.2	59.9	4%
<b>Total Hexvix/Cysview</b>	<b>46.3</b>	<b>36.3</b>	<b>28%</b>	<b>172.9</b>	<b>145.6</b>	<b>19%</b>
Other revenue	3.5	0.8		8.6	5.3	
<b>Total revenue</b>	<b>49.9</b>	<b>37.1</b>	<b>34%</b>	<b>181.5</b>	<b>150.9</b>	<b>20%</b>
Operating expenses	-43.6	-35.0	24%	156.0	128.5	21%
<b>EBITDA recurring</b>	<b>1.3</b>	<b>-1.3</b>		<b>8.4</b>	<b>10.4</b>	
<b>Development Portfolio</b>						
Operating expenses	-5.4	-11.8	-54%	-18.9	-39.5	-52%
<b>EBITDA recurring</b>	<b>-5.4</b>	<b>-11.8</b>		<b>-18.9</b>	<b>-39.5</b>	
<b>TOTAL</b>						
<b>EBITDA recurring</b>	<b>-4.1</b>	<b>-13.1</b>		<b>-10.5</b>	<b>-29.1</b>	

The statement is prepared on the proforma basis as if the accounting principles IFRS 15 and IFRS 9 had been adopted 1 Jan '17

### Commercial Franchise

- Strong revenue growth in US, fourth quarter revenue growth in US\$ 76%, full year 53%
  - Installed base of BLC year end at 157, increased 51% for the full year
- Continued growth in Nordic, 5% in Q4
- Partner revenue Q4 growth 9%, driven by Canada (BioSyent) and Germany (Ipsen)
- Increased operating expenses driven by commercial investments in US

### Development Portfolio

- Significant cost reduction – activity level and capacity reductions

# CONSOLIDATED INCOME STATEMENT - PROFORMA

## FOURTH QUARTER 2018

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<b>Total revenue</b>	<b>49.9</b>	<b>37.1</b>	34%	<b>181.5</b>	<b>150.9</b>	20%
<b>Gross profit</b>	<b>44.9</b>	<b>33.7</b>	33%	<b>164.4</b>	<b>138.9</b>	18%
Operating expenses	-49.0	-46.8	5%	-174.9	-168.0	4%
<b>EBITDA recurring</b>	<b>-4.1</b>	<b>-13.1</b>		<b>-10.5</b>	<b>-29.1</b>	
Depreciation & Amort.	-3.4	-3.6		-13.2	-13.1	
Restructuring expenses	-1.1			-14.2		
One-off items					-4.0	
<b>EBIT</b>	<b>-8.6</b>	<b>-16.6</b>		<b>-37.9</b>	<b>46.2</b>	
Net financial items	1.2	1.0		1.2	3.6	
<b>Earnings before tax</b>	<b>-7.3</b>	<b>-15.7</b>		<b>-36.7</b>	<b>-42.6</b>	
Tax expenses	-4.6	0.2		0.0	6.9	
<b>Net earnings</b>	<b>-12.0</b>	<b>-15.5</b>		<b>-36.7</b>	<b>-35.7</b>	

- Recurring EBITDA significantly improved from last year. Improvement is revenue driven while expense growth is limited
  - Increased Hexvix/Cysview revenue driven by US
  - Increased sales & marketing expenses, partly offset by decline in R&D and other operating expenses, net growth 4%
- Depreciation and amortization driven by amortization of Cysview phase 3 investments
- Restructuring expenses NOK 14.2 million, headcount reductions and organizational changes in second quarter

The statement is prepared on the proforma basis as if the accounting principles IFRS 15 and IFRS 9 had been adopted 1 Jan '17



# CASH FLOW

## FOURTH QUARTER 2018

<i>Amounts in NOK million</i>	Q4 '18	Prof Q4 '17	FY '18	Prof FY '17
<b>Operations cash flow</b>	<b>11.2</b>	<b>7.5</b>	<b>-24.1</b>	<b>-23.6</b>
EBITDA, recurring	-4.1	-10.8	-10.5	-29.1
Working capital	11.9	17.1	1.4	6.4
Other	3.3	1.2	-15.0	-0.9
<b>Investments cash flow</b>	<b>-0.4</b>	<b>-1.2</b>	<b>-1.1</b>	<b>-16.3</b>
Development exp.	-	-0.8	-0.6	-17.5
Other	-0.4	-0.4	-0.5	1.3
<b>Financing cash flow</b>	<b>3.2</b>	<b>-</b>	<b>2.7</b>	<b>-</b>
Share capital	6.3	-	6.3	-
Other	-3.1	-	-3.7	-
<b>Net change in cash</b>	<b>14.0</b>	<b>6.3</b>	<b>-22.5</b>	<b>-39.9</b>
<b>Ending cash balance</b>	<b>106.8</b>	<b>129.4</b>	<b>106.8</b>	<b>129.4</b>

- Cash flow from operations fourth quarter at NOK 11.2 million, full year NOK -24.1 million
  - Working capital positive in the quarter, main drivers are funds from Skattefunn (tax incentive scheme) and increased payables.
- Cash flow from investments fourth quarter NOK -0.4 million, full year NOK -1.1 million
  - Full year improvement of NOK 15.2 million from 2017. Decline driven by investments in development projects as Cysview phase 3 project is finalized
- Year end cash balance at NOK 106.8 million

# BALANCE SHEET

## 31 DECEMBER 2018

<i>Amounts in NOK million</i>	<b>31.12 2018</b>	<b>31.12. 2017</b>
Non current assets	77.8	87.5
Investments	24.6	34.6
Tax asset	52.4	52.9
Other	0.7	-
Inventory & receivables	46.6	46.2
Cash & equivalents	106.8	129.4
<b>Total assets</b>	<b>231.2</b>	<b>263.1</b>
Shareholders equity	176.3	218.1
Long term liabilities	2.5	4.8
Current liabilities	52.3	40.3
<b>Total equity &amp; liabilities</b>	<b>231.2</b>	<b>263.1</b>
<i>Equity ratio</i>	76%	83%

- Investments of NOK 24.6 million in tangible and intangible assets is driven by investments in Cysview phase 3 project
- Deferred tax asset of NOK 52.4 million at level with YE 2017, tax rate reduced from 23% to 22%
- No interest bearing debt
- Shareholder's equity of NOK 176.3 million. Equity ratio of 76%

# *Summary and Outlook*



# OUTLOOK

.....



## Growth drivers USA

- 50% Larger customer facing commercial team
- Target 700 largest reference center hospitals and LUGPAs
- BLC Recommended in AUA & NCCN bladder cancer treatment guidelines
- Improved permanent favorable reimbursement
- Accelerated penetration into large untapped surveillance market

## Growth drivers Europe

- Strongly recommended by European and national guidelines
- Strengthened customer facing commercial team in Nordic
- Penetration into European surveillance market

## Financial guidance

- 2020 revenue outlook (U.S.) will remain \$20-25 million
- Significant continued revenue growth and profit opportunities in the U.S. market beyond 2020



# INCOME STATEMENT

## FOURTH QUARTER REPORTED

### Income Statement - Segment

<i>MNOK</i>	<u>Q4 '18</u>	<u>Q4 '17</u>	<u>FY '18</u>	<u>FY '17</u>
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Operating expenses	-43.6	-35.1	-156.0	-128.5
<b>EBITDA recurring</b>	<b>1.3</b>	<b>0.9</b>	<b>8.4</b>	<b>10.4</b>
<u>Development Portfolio</u>				
Operating expenses	-5.4	-11.8	-18.9	-39.5
<b>EBITDA recurring</b>	<b>-5.4</b>	<b>-11.8</b>	<b>-18.9</b>	<b>-39.5</b>
<u>Total</u>				
<b>EBITDA recurring</b>	<b>-4.1</b>	<b>-10.8</b>	<b>-10.5</b>	<b>-29.1</b>

### Income Statement - Consolidated

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One-Off items	-	-	-	-4.0
<b>EBIT</b>	<b>-8.6</b>	<b>-14.1</b>	<b>-37.9</b>	<b>-45.2</b>
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<b>Earnings before tax</b>	<b>-7.3</b>	<b>-13.2</b>	<b>-36.7</b>	<b>-41.6</b>
Tax expenses	-4.6	0.2	0.0	6.9
<b>Net earnings</b>	<b>-12.0</b>	<b>-13.0</b>	<b>-36.7</b>	<b>-34.7</b>