

# PHOTOCURE ASA END OF YEAR 2019 & Q4 PRESENTATION

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THE  
BLADDER CANCER  
COMPANY™

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# 2019 HIGHLIGHTS AND SUBSEQUENT EVENTS

## Financial growth highlights:

- Positive growth rates in Nordics, US and Partner countries
- US: Strong revenue growth, in USD FY 43%
  - US accounts for nearly 50% of our total sales revenue
- Installed base of rigid and flex BLC 223 (of which 26 flexible scopes) at year-end, increased 42% YOY
- Positive EBITDA: NOK 54.8 million for the quarter

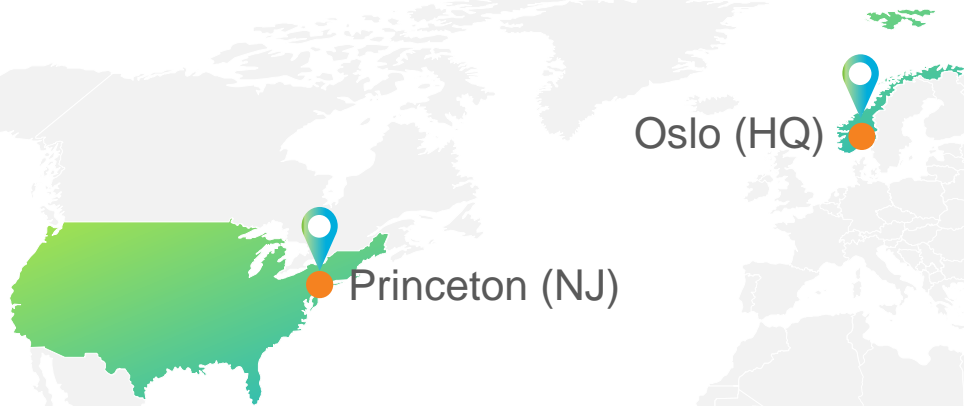
## Partnership highlights:

- Partner markets grew at 7% YOY
- Asieris payment of USD 5 million in Q3 & Q4 2019

## Product highlights:

- Publication at BLADDR congress: Recent early stage studies show a potential treatment effect of Blue Light Cystoscopy (BLC™) with Hexvix<sup>1</sup>
- Publication in Urology: Reduced recurrence after flexible Blue Light Cystoscopy with Hexvix in surveillance
- US patent for neoadjuvant therapy for patients scheduled for cystectomy (Expiry 2036)

# PHOTOCURE AT A GLANCE



- » Norwegian **commercial-stage pharmaceutical company** focused on bladder cancer with **commercial operations** in Nordics and USA. **Partners** in Europe, Canada, Australia and New Zealand

## CORE PRODUCT ON MARKET

**HEXVIX®**  
Hexaminolevulinate 85mg

**CYSVIEW®**  
Hexaminolevulinate HCl

**Bladder cancer detection & management**

## Accelerating revenue growth:

» **+23%** total sales revenue growth in 2019

» **USD 37M** global in-market sales\*

» **500 000+** patients treated with Hexvix / Cysview worldwide

» **USD 220M** Market cap\*\*

» **175K** Avg daily volume LTM

» Oslo Stock Exchange:  
**IPO May 2000**

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

\*\* One month average



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# PHOTOCURE BEFORE AND NOW:



**Global Leader in  
Photodynamic  
Therapy (PDT)**

**As of 1997**



**New strategic focus:**

**The Bladder Cancer  
Company**

**2018**



**Continue success of  
Hexvix/Cysview**

**Expand portfolio of  
bladder cancer  
assets**

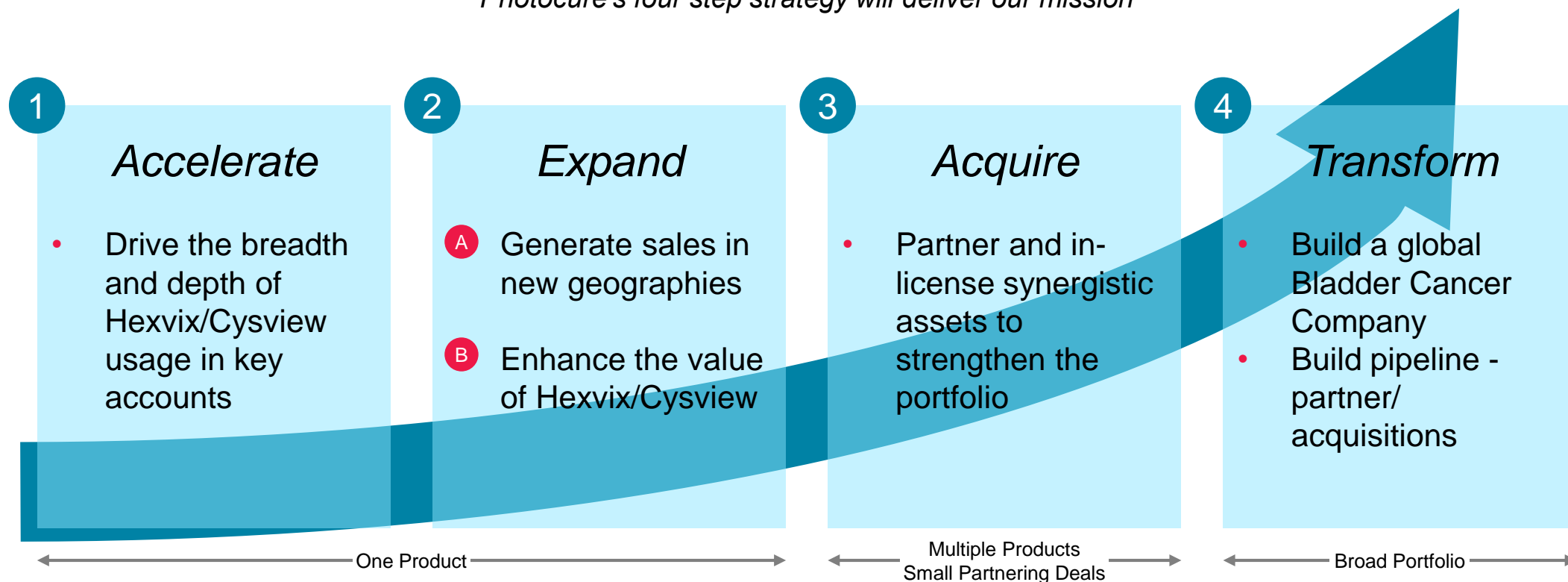
**2020 + beyond**



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# OUR MISSION IS TO DELIVER TRANSFORMATIVE SOLUTIONS WHICH IMPROVE THE LIVES OF BLADDER CANCER PATIENTS

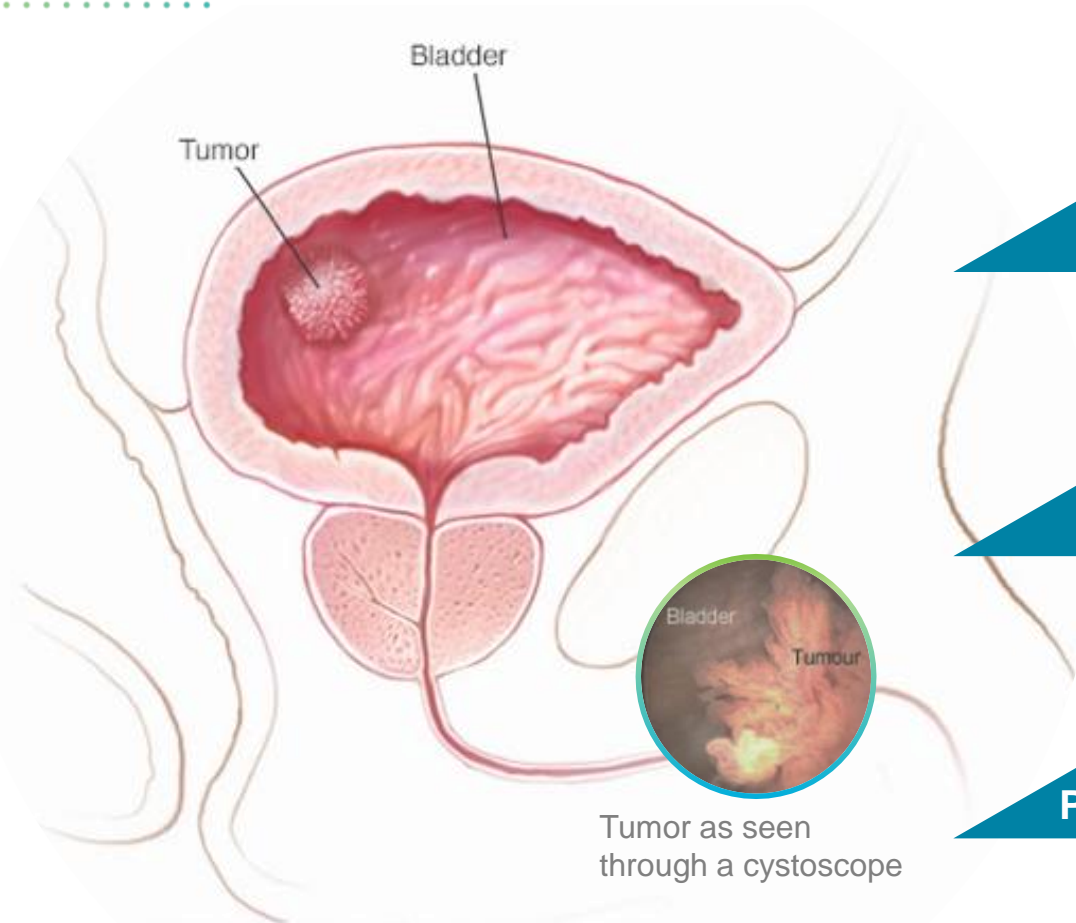
*Photocure's four step strategy will deliver our mission*



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



# LARGE UNMET NEEDS IN NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC)



COMMON

9<sup>th</sup>

most common  
cancer worldwide<sup>1</sup>

550,000

new cases<sup>1</sup>

200,000

deaths annually  
of which 75% are men<sup>1</sup>

EXPENSIVE

#1

Highest per patient  
lifetime treatment costs  
of any cancer<sup>2</sup>

USD 5.7 Billion

Cost of Bladder Cancer in the US,  
projection for 2020<sup>3</sup>

RECURRING

61%

recurrence  
in 1 year<sup>4</sup>

78%

recurrence  
in 5 years<sup>4</sup>

PROGRESSING

2% – 50%

Disease progression from NMIBC to MIBC<sup>4</sup>

DEBILITATING



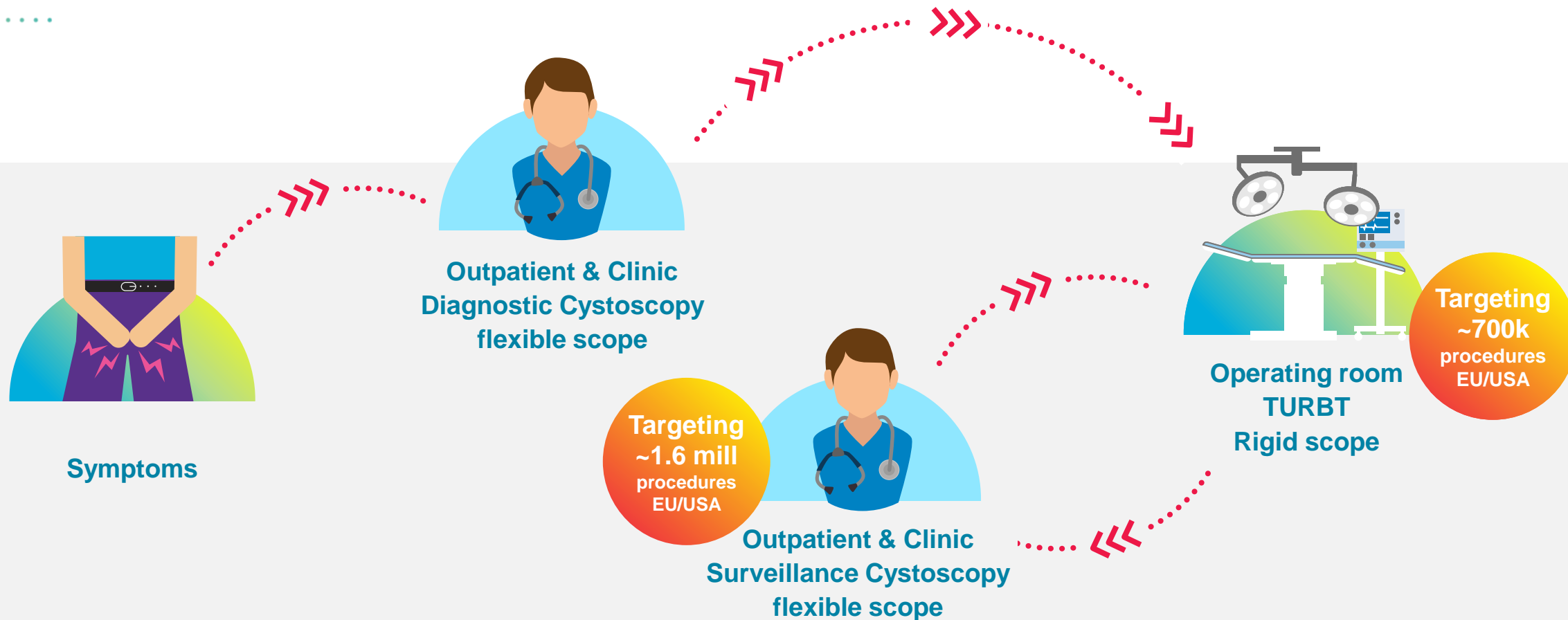
Lifelong follow-up  
with repeat TURBTs and cystoscopies



Potential urinary dysfunction, patient fear,  
anxiety and confusion

1. Globocan. Incidence/mortality by population. Available at: [http://globocan.iarc.fr/Pages/bar\\_pop\\_sel.aspx](http://globocan.iarc.fr/Pages/bar_pop_sel.aspx)  
 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, Global Data: Bladder Cancer Report,

# THE PATIENT JOURNEY – CHARACTERIZED BY LONG TERM FOLLOW-UP WITH REPEAT PROCEDURES



Hexvix®/Cysview®: Use for the 1st TURBT and for all intermediate and high-risk NMIBC patients during surgical treatment and surveillance / follow-up

\*TURBT: trans-urethral resection of bladder tumors



# HEXVIX®/CYSVIEW® FOR BETTER DETECTION AND MANAGEMENT OF NMIBC

**HEXVIX®**  
Hexaminolevulinate 85mg

**CYSVIEW®**  
Hexaminolevulinate HCl

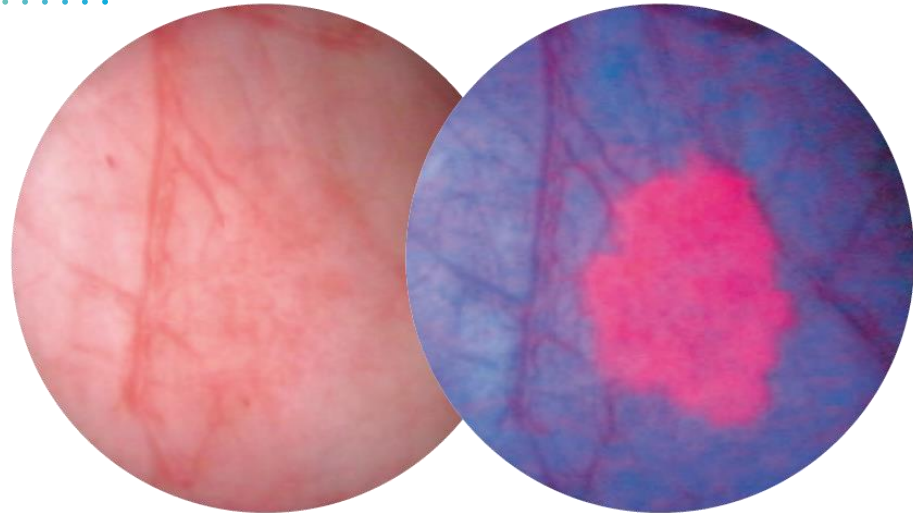
is taken up selectively  
by cancer cells in  
the bladder  
making **them**  
**glow bright pink**  
**under blue light**

◀◀ A Drug Device combination  
for better visual contrast  
between benign  
and malignant cells ▶▶

Hexvix / Cysview is used  
with a **blue light enabled**  
**cystoscope**, from Karl  
Storz, Wolf or Olympus

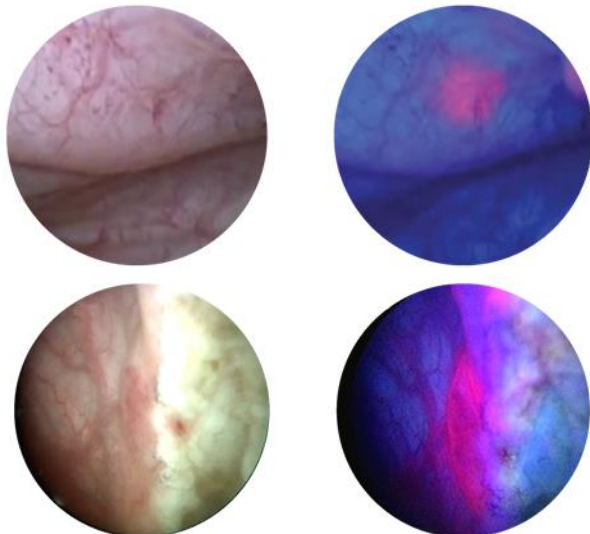


# “YOU CANNOT TREAT WHAT YOU CANNOT SEE!”



White Light Cystoscopy (WLC)

Blue Light Cystoscopy (BLC™)  
with Hexvix®/Cysview®



Risk that 20-35% of cancer patients will be missed, if Blue Light Cystoscopy is NOT used<sup>1,2</sup>



Risk of wrong risk-classification leading to mis-management of disease, if Blue Light Cystoscopy is NOT used



Incomplete resection of bladder tumors leading to increased risk of recurrence and progression to more advanced disease, if Blue Light Cystoscopy is NOT used

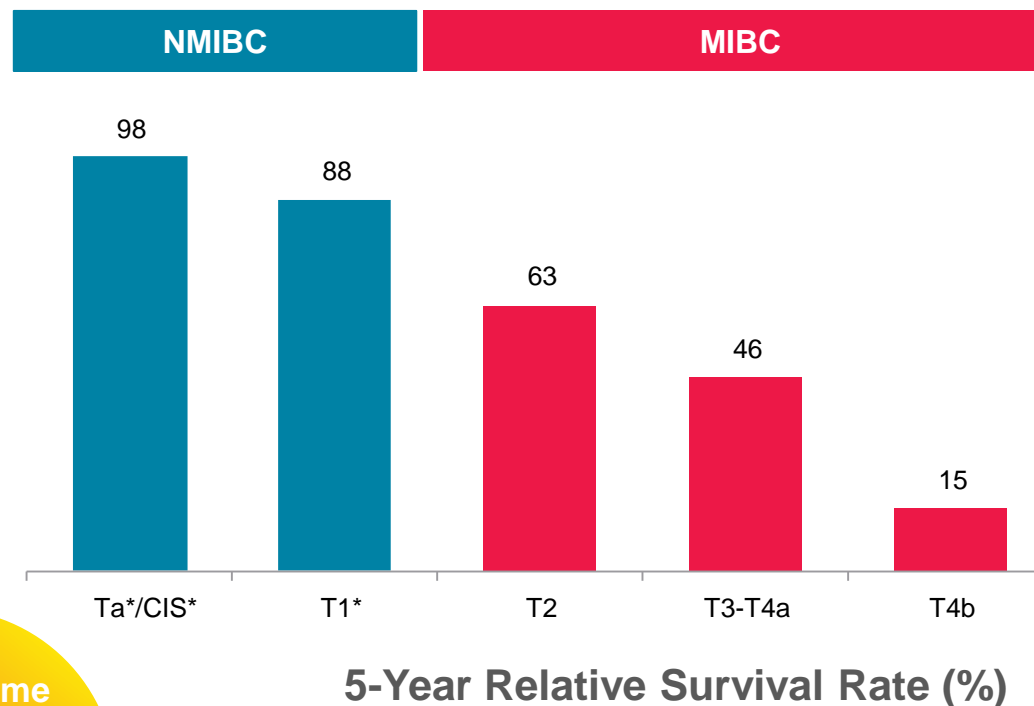
# BLUE LIGHT CYSTOSCOPY CAN PROVIDE AN ACCURATE AND COMPLETE 1ST TURBT – CRITICAL FOR PATIENT OUTCOMES

## Bladder Cancer Progression and Recurrence

**Key therapeutic aim is to avoid progression from non-muscle invasive bladder cancer (“NMIBC”) to muscle invasive bladder cancer (“MIBC”)**

- » The first TURBT is essential for patient outcomes: correct diagnosis, complete removal of all lesions.<sup>2</sup>
- » The two most important factors for progression to MIBC:
  - presence of CIS\*, the flat and hard to detect lesions with a high tendency to progress
  - presence of high grade tumor

**For the same patient having CIS more than doubles their probability to progress to MIBC**



\* Ta, T1, CIS: Non muscle invasive bladder cancer tumor types

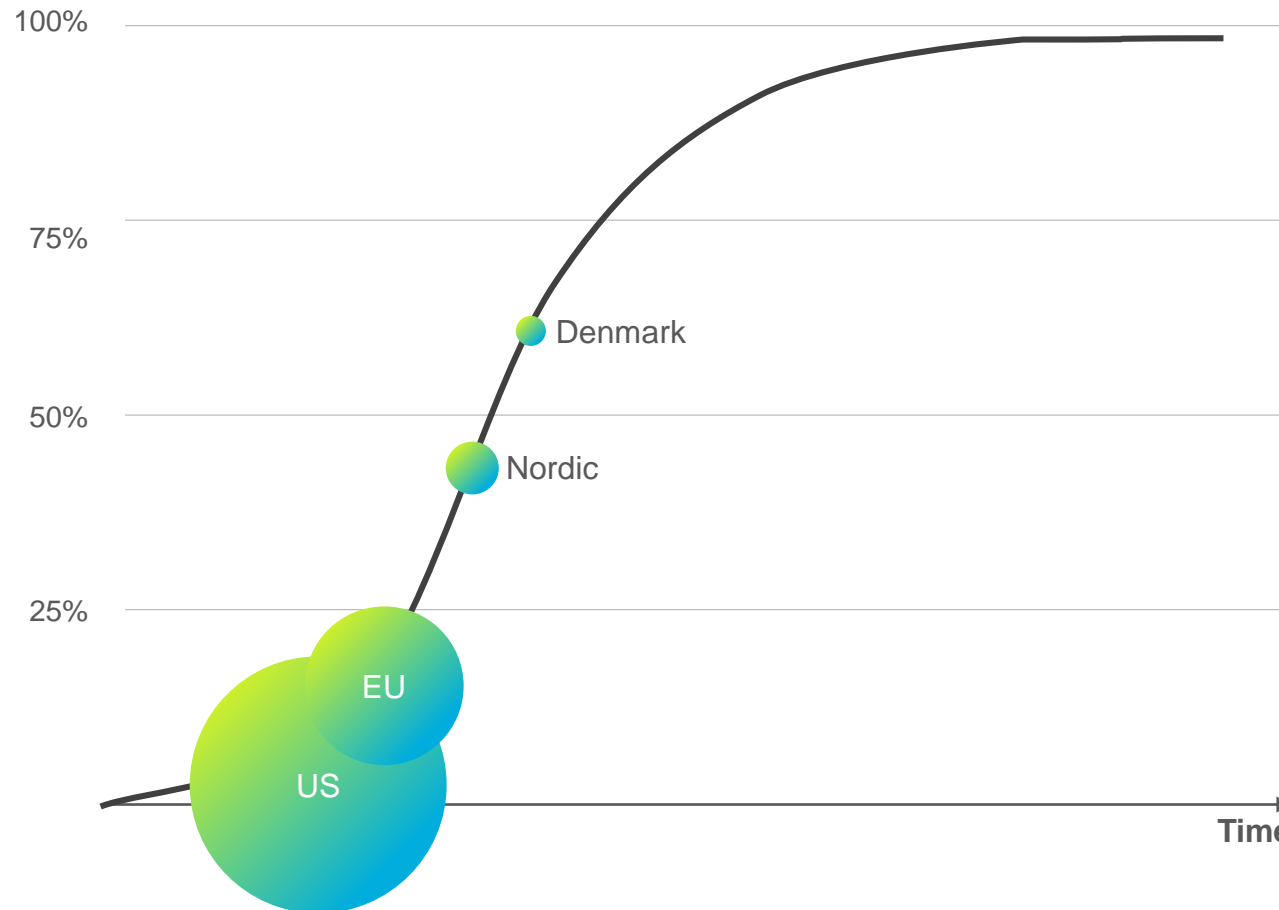
*Positioned for growth*



# HEXVIX®/CYSVIEW® – KEY ENABLERS IN PLACE AND READY FOR GROWTH

Penetration

POSITION IN THE LIFE CYCLE



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

# SUPPORTIVE ENVIRONMENT & INCREASING AWARENESS

## FOR BECOMING THE STANDARD OF CARE FOR THE DETECTION AND MANAGEMENT OF BLADDER CANCER

- **Inclusion in Bladder Cancer treatment guidelines**

BLC™ with Hexvix® /Cysview® is strongly recommended by US, European and national guidelines as well as expert panels.



American  
Urological  
Association



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

- **High adoption rate in top Cancer centers**

Established in >170 key US cancer hospitals and leading institutions.

- **Patient preference**

growing awareness and active preference as shown in recent BCAN survey

- **Favorable and Permanent US Reimbursement 2019**

further improvements from January 2020

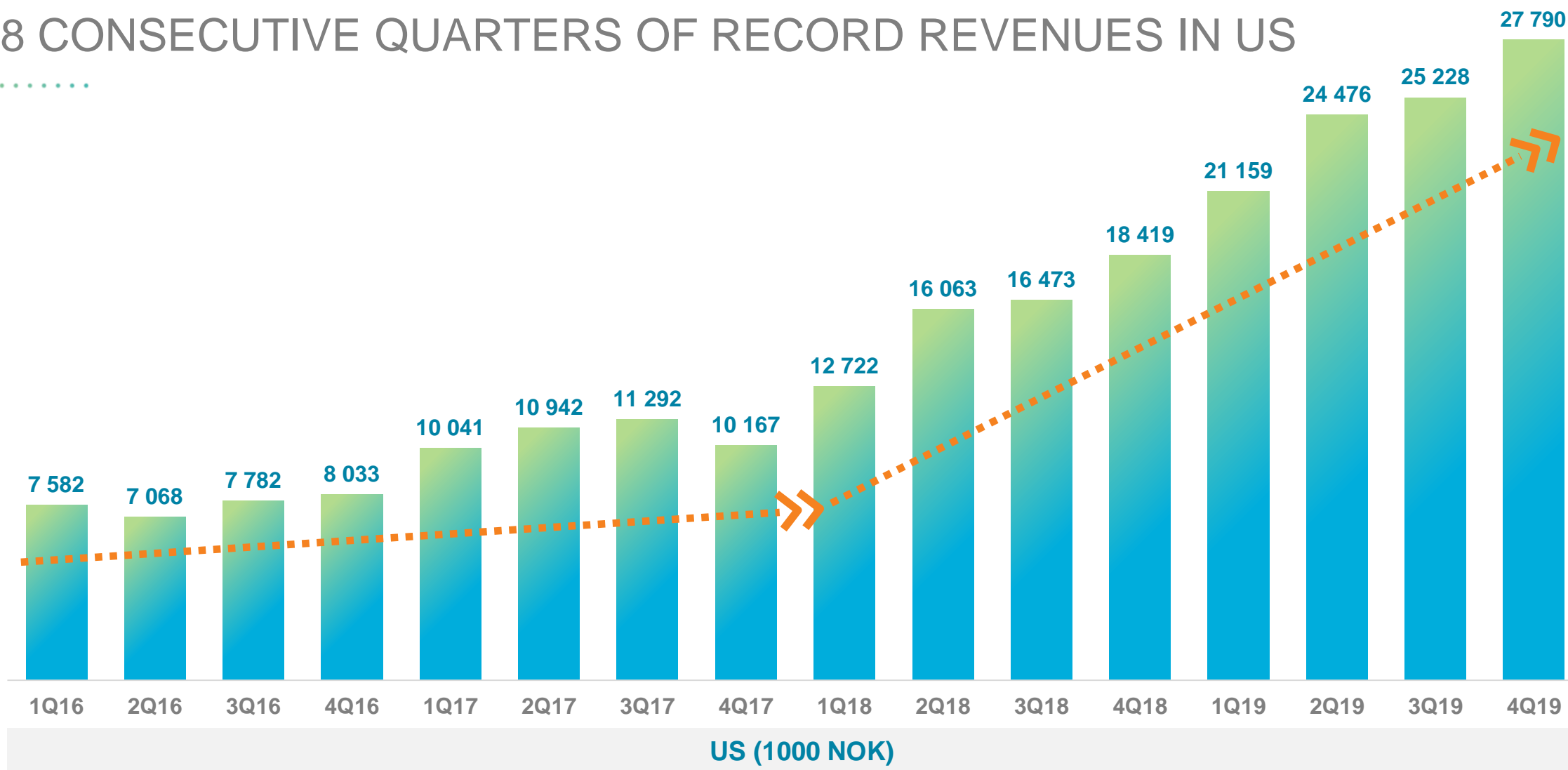
- **Partnering with prominent Patient Associations**

especially BCAN in the US and the new World Bladder Cancer Patient Coalition



# US: ACCELERATED MOMENTUM

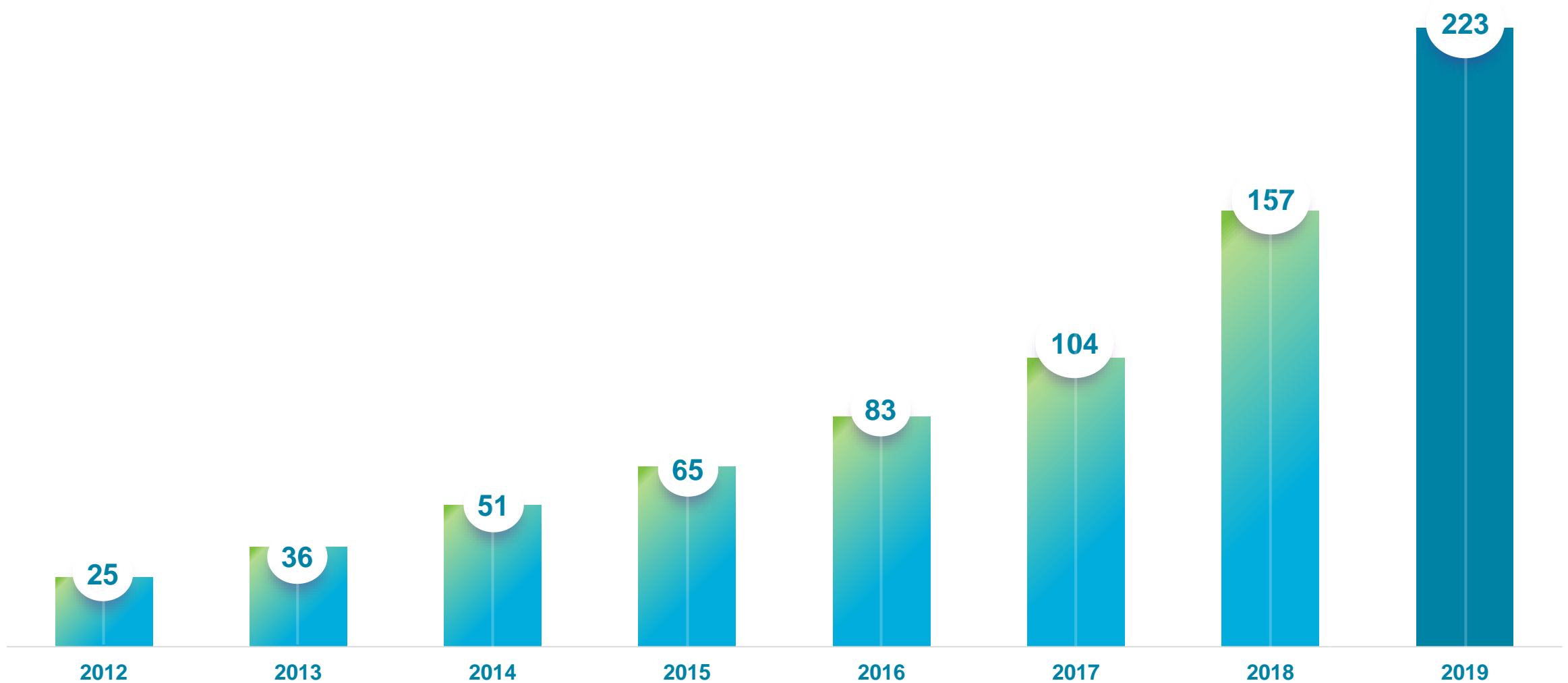
## 8 CONSECUTIVE QUARTERS OF RECORD REVENUES IN US





# US: ACCELERATED MOMENTUM

## INSTALLED BASE OF CYSTOSCOPES IN THE US



# US: THE INVESTMENT MADE WILL DELIVER ACCELERATED RETURNS



## Strategy – Target Key Hospitals in the 30 largest MSAs in the US

2018/19 – We have built the Commercial Foundation

- Sales team focused on top 700+ centers that influence bladder cancer care in their regions
- Team is composed of 28 Surgical Sales Executives (“hunters” – sell to new accounts) and 5 Clinical Support Specialists (“farmers” – increase utilization of current accounts)
- Average territory for sales rep at peak sales: USD 1.5 - 2 mill in revenues
- Future investment would be predicated on gaining optimal account coverage with similar ROI
- Continuous improvement to build a performance driven culture

# HEXVIX®/CYSVIEW® FUTURE POTENTIAL: THERAPEUTIC PATENT SECURED



- Recent early stage studies show a potential treatment effect of Blue Light Cystoscopy (BLC™) with Hexvix<sup>1</sup>

Study results: a treatment effect could be related to

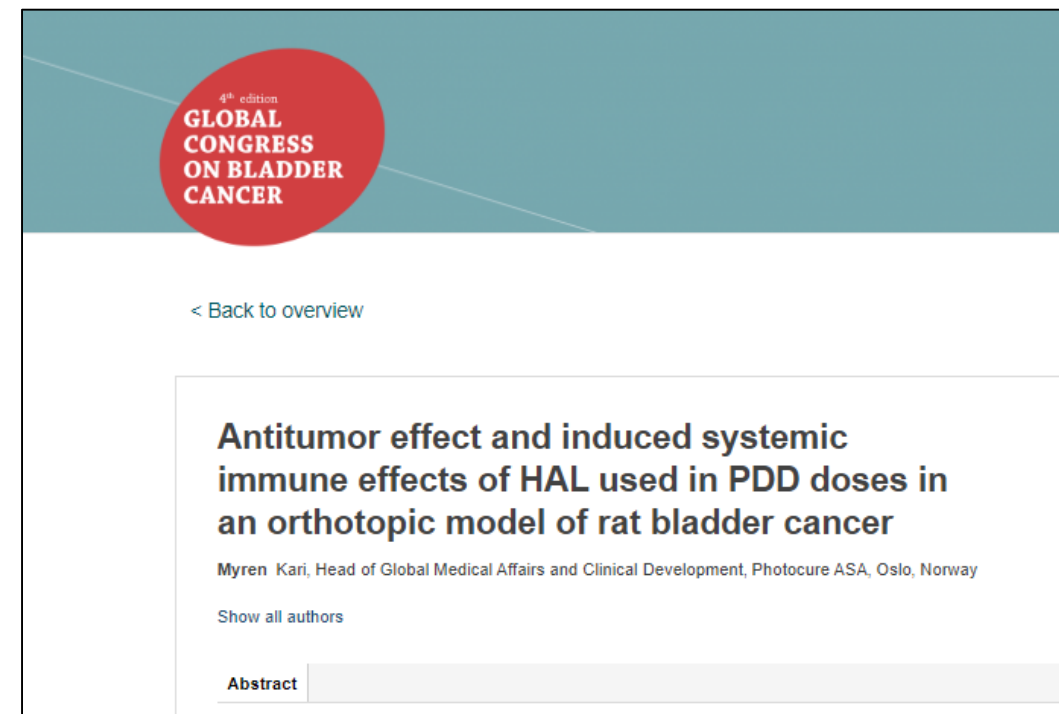
- direct anti-tumor effect
- immune cell activation

- Photocure has the intention to further explore areas of utility of Hexvix/Cysview

- Therapeutic effect

**US Patent issued Feb 11<sup>th</sup> 2020 covering the use of Hexvix as a neoadjuvant agent in the treatment of patients scheduled for cystectomy**

- Other areas of early investigation include enhancing the detection and physician experience and the use of Hexvix/Cysview in combination therapy



# *IP Strategy*



# DRUG-DEVICE COMBINATION – HURDLES TO MARKET ENTRY

NO PDT PRODUCTS HAVE EXPERIENCED GENERIC COMPETITION (VISUDYNE, METVIX) TO DATE

1

## IP\*/Intellectual Property

Review multiple patents, regulatory data protection in the US with market exclusivity for office use/flex

2

## Desk research/Market size

No straightforward access to sales data and performance – different hospital distribution paths, ATC classification “Other diagnostics”

3

## Technical/Manufacturing hurdles

API manufacturing or sourcing – meet *EU/US pharmacopeia monograph specifications*

Freeze dry API under aseptic conditions.  
Solvent in vial or prefilled syringe.  
Manual/semi manual packaging/labeling

Photocure exclusivity with only commercial medical API supplier in the world

4

## Regulatory hurdles

A drug-device combination product. ANDA<sup>1</sup> for drug, PMA<sup>2</sup> for device. Multiple FDA offices. Participation by 2 companies, requires device manufacturer relationship and coordinated process

No clear drug approval standard: How to document “bioequivalence?”

Note: 1) Abbreviated new drug application;  
2) Premarket approval

5

## Commercial challenges

Active product support incl. training of physicians and nurses, facilitate workflow

IN ADDITION, PHOTOCURE IS CONTINUOUSLY FOCUSING ON **KEY STRATEGIC INITIATIVES** TO FURTHER STRENGTHEN ITS LONG-TERM COMPETITIVENESS



# *Cevira® License Agreement*





# CEVIRA®: LICENSE AGREEMENT WITH ASIERIS

ASIERIS MEDITECH  
CO., Ltd.



- Asieris is a subsidiary of the China-based Jiangsu Yahong Meditech Co., Ltd., a specialty pharma company
- Strong development capabilities in genitourinary diseases (GU) area in China, rapidly expanding its global capability
- Leading drug candidate for treating non-muscle invasive bladder cancer, is in a registrational clinical trial in China and Phase Ib trial in the US

## CEVIRA® – CERVICAL CANCER



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

## License Agreement terms: USD 250 mill potential in total:

- » Under the License Agreement, Photocure will receive a total signing fee of USD 5 million within 6 months after signing
- » Approval of the initial indication will result in USD 18 million in China (est 2024) and USD 36 million in US/EU (est 2026)
- » A second indication in China, the US and the EU would result in payments of up to USD 14 million
- » Sales royalties and milestones will apply in all markets



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# *Q4 2019 Financials*



# SEGMENT PERFORMANCE

## FOURTH QUARTER 2019

<i>Amounts in NOK million</i>	Q4 '19	Q4 '18	Change	FY '19	FY '18	Change
<b>Commercial Franchise</b>						
Nordic revenue	14.5	13.5	7%	48.2	47.0	3%
US revenue	27.8	18.4	51%	98.7	63.7	55%
Partner revenue	16.5	14.4	14%	66.3	62.2	7%
<b>Total Hexvix/Cysview</b>	<b>58.8</b>	<b>46.3</b>	27%	<b>213.2</b>	<b>172.9</b>	23%
Other revenue	0.3	3.5		3.2	8.6	
<b>Total revenue</b>	<b>59.1</b>	<b>49.9</b>	19%	<b>216.4</b>	<b>181.5</b>	19%
Operating expenses	-49.7	-43.6	14%	-186.6	-156.0	20%
<b>EBITDA ex restruct.</b>	<b>1.6</b>	<b>1.3</b>		<b>7.3</b>	<b>8.4</b>	
<b>Development Portfolio</b>						
<b>Total revenue</b>	<b>56.4</b>	-		<b>65.1</b>	-	
Operating expenses	-3.3	-5.4	-39%	-13.5	-18.9	-28%
<b>EBITDA ex restruct.</b>	<b>53.2</b>	<b>-5.4</b>		<b>51.6</b>	<b>-18.9</b>	
<b>TOTAL</b>						
<b>EBITDA ex restruct.</b>	<b>54.8</b>	<b>-4.1</b>		<b>58.9</b>	<b>-10.5</b>	

### Commercial Franchise

- US: Strong revenue growth, in USD Q4 39% and FY 43%
  - Installed base of rigid and flex BLC 223 at quarter end, increased 42% YOY
- Nordic: Q4 revenue growth 7%, FY growth 3%, partly driven by high December sales in Denmark
- Partner: Revenue growth in Q4 14%. FY growth 7%, driven by Germany and France (Ipsen)
- Increased operating expenses, Q4 at 14% YOY, commercial investments in US

### Development Portfolio

- Revenue FY from Asieris, USD 8.0 million, of which USD 5 million paid in Q4 and USD 3 million accrued as per IFRS 15
- Operating expenses Q4 and YTD include one-off costs related to agreement with Asieris

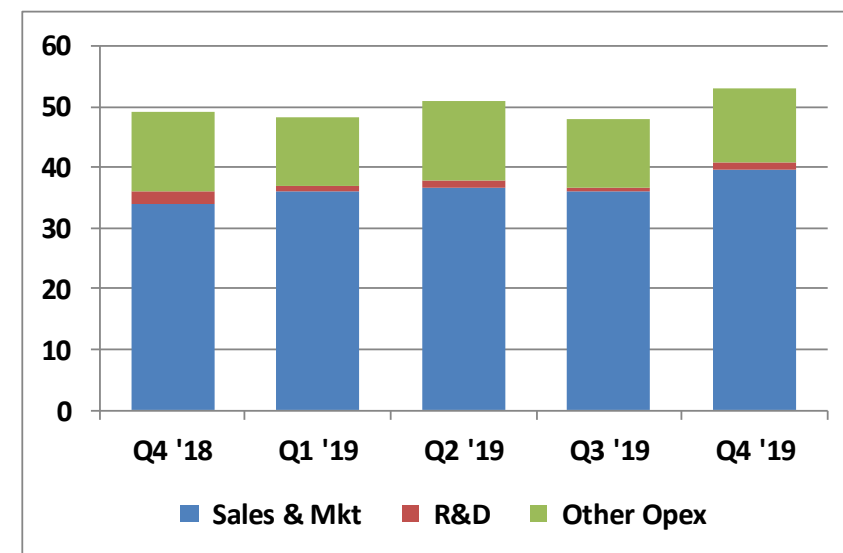
# CONSOLIDATED INCOME STATEMENT

## FOURTH QUARTER 2019

<i>Amounts in NOK million</i>	Q4 '19	Q4 '18	Change	FY '19	FY '18	Change
Hexvix/Cysview revenue	58.8	46.3	27%	213.2	172.9	23%
Other revenue	56.8	3.5		68.3	8.6	
<b>Total revenue</b>	<b>115.6</b>	<b>49.9</b>	<b>132%</b>	<b>281.6</b>	<b>181.5</b>	<b>55%</b>
<b>Gross profit</b>	<b>107.7</b>	<b>44.9</b>	<b>140%</b>	<b>259.0</b>	<b>164.4</b>	<b>58%</b>
Operating expenses	-52.9	-49.0	8%	-200.1	-174.9	14%
<b>EBITDA ex restruct.</b>	<b>54.8</b>	<b>-4.1</b>		<b>58.9</b>	<b>-10.5</b>	
Depreciation & Amort.	-3.8	-3.4		-16.2	-13.2	
Restructuring expenses	-	-1.1		-	-14.2	
<b>EBIT</b>	<b>51.0</b>	<b>-8.6</b>		<b>42.7</b>	<b>-37.9</b>	
Net financial items	2.3	1.2		3.2	1.2	
<b>Earnings before tax</b>	<b>53.3</b>	<b>-7.3</b>		<b>45.9</b>	<b>-36.7</b>	
Tax expenses	-10.7	-4.6		-14.1	-	
<b>Net earnings</b>	<b>42.5</b>	<b>-12.0</b>		<b>31.8</b>	<b>-36.7</b>	

- Operating expenses, increase driven by
  - Planned investments in US commercial operations (sales & marketing)
  - Business development expenses particularly related to Cevira (other operating expenses)
  - Significant FX impact: Growth in constant currencies FY approx. 9%

Operating expenses, quarterly (NOK million)



# CASH FLOW

## FOURTH QUARTER 2019

<i>Amounts in NOK million</i>	Q4 '19	Q4 '18	FY '19	FY '18
<b>Operations cash flow</b>	<b>30.4</b>	<b>11.2</b>	<b>20.7</b>	<b>-24.1</b>
Earnings before tax	53.3	-7.3	45.9	-36.7
Working capital	3.1	11.9	-7.1	1.4
Other	-26.0	6.6	-18.2	11.2
<b>Investments cash flow</b>	<b>-</b>	<b>-0.4</b>	<b>0.6</b>	<b>-1.1</b>
Development exp.	-0.2	-	-0.3	-0.6
Other	0.2	-0.4	0.9	-0.5
<b>Financing cash flow</b>	<b>-1.0</b>	<b>3.2</b>	<b>-2.8</b>	<b>2.7</b>
Share capital	-	6.3	0.6	6.3
Other	-1.0	-3.1	-3.4	-3.7
<b>Net change in cash</b>	<b>29.4</b>	<b>14.0</b>	<b>18.5</b>	<b>-22.5</b>
<b>Ending cash balance</b>	<b>125.3</b>	<b>106.8</b>	<b>125.3</b>	<b>106.8</b>

- Cash flow from operations Q4 and FY improved due to sign-on payments from Asieris.
  - Other operations cash flow includes deferred revenue from the Asieris contract.
- Cash flow from financing includes payment of lease liability totaling NOK 1.0 million in Q4 and FY NOK 3.4 million in 2019
- Net change in cash improved NOK 15.4 million in Q4 and FY NOK 41.0 million compared to last year
- Year end cash balance at NOK 125.3 million

# BALANCE SHEET

## 31 DECEMBER 2019

<i>Amounts in NOK million</i>	<b>31.12 2019</b>	<b>31.12 2018</b>
Non current assets	70.5	77.8
Investments	13.6	24.6
Tax asset	38.3	52.4
Other	18.5	0.7
Inventory & receivables	61.6	46.6
Cash & equivalents	125.3	106.8
<b>Total assets</b>	<b>257.4</b>	<b>231.2</b>
Shareholders equity	208.6	176.3
Long term liabilities	10.0	2.5
Current liabilities	38.7	52.3
<b>Total equity &amp; liabilities</b>	<b>257.4</b>	<b>231.2</b>
<i>Equity ratio</i>	<i>81%</i>	<i>76%</i>

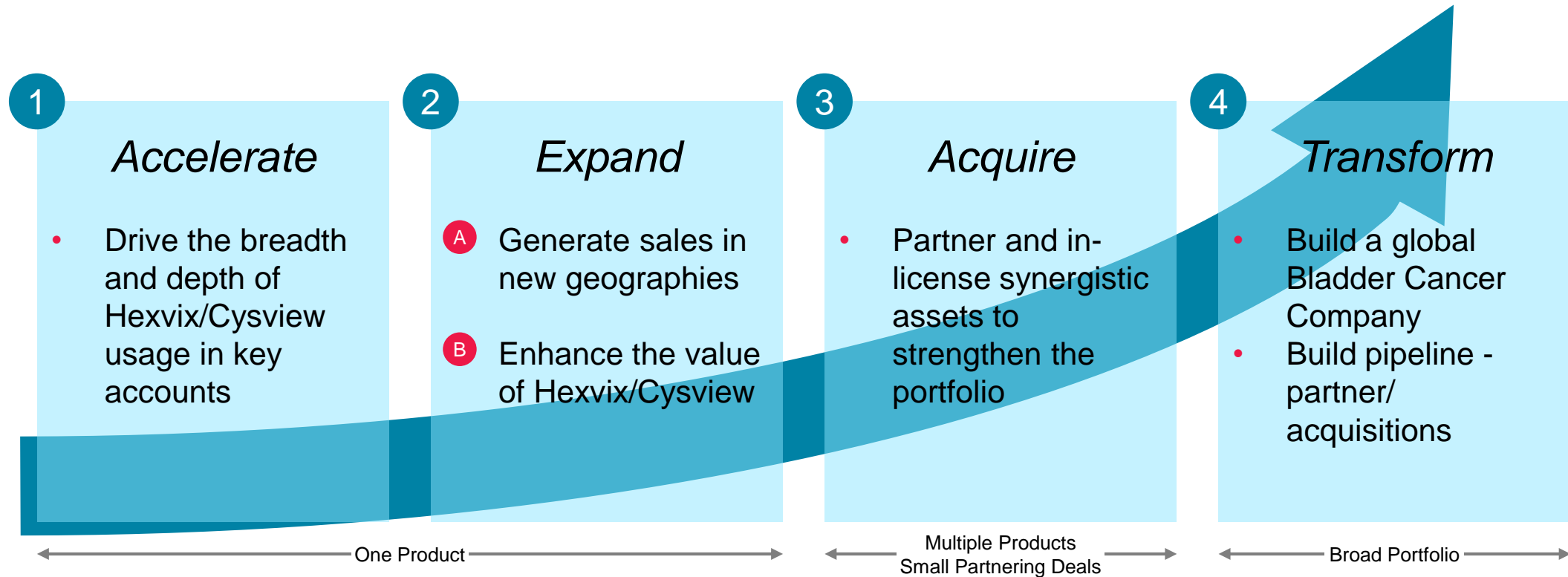
- Non current assets
  - Investments of NOK 13.6 million in tangible and intangible assets is driven by investments in Cysview phase 3 project
  - Deferred tax asset of NOK 38.3 million
  - Other items includes impact from adoption of IFRS 16 (Leases) as well as the long term part of the Asieris receivable
- Inventory & receivables driven by Hexvix/Cysview revenue increase and by the short-term part of the Asieris receivable
- Long term liabilities include impact from adoption of IFRS 16 (Leases) from 1 January 2019
- No interest bearing debt
- Shareholder's equity of NOK 208.6 million  
Equity ratio of 81%

# *Summary and outlook*





# CREATING THE LEADING BLADDER CANCER COMPANY



Ambition of US revenues of USD 70 million in 2023  
with significant and sustainable revenue growth in the US market beyond 2023

*Q&A*

