### PHOTOCURE ASA RESULTS FOR 1<sup>ST</sup> QUARTER 2020

7 May 2020

Daniel Schneider, President and CEO Erik Dahl, CFO





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### 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**





**Bladder cancer detection & management** 

# Accelerating revenue growth:

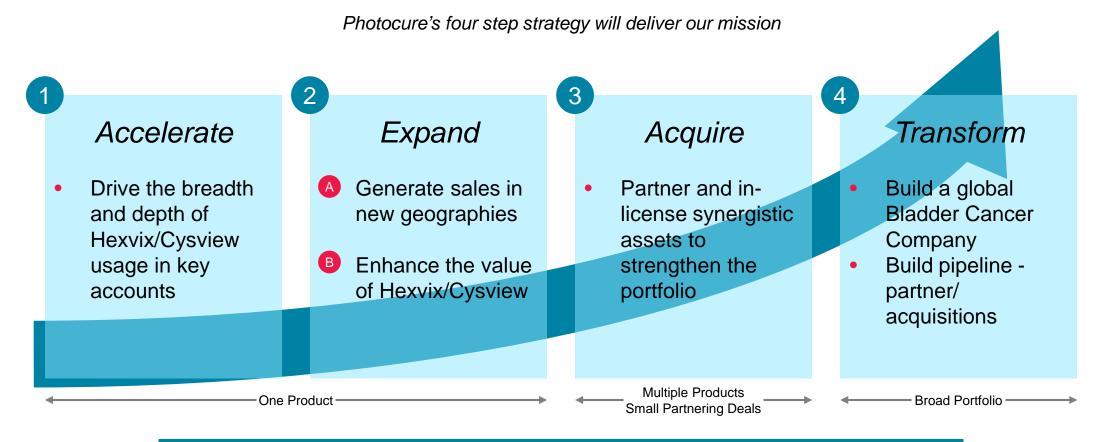
- **+23%** total sales revenue growth in 2019
- NOK 330M global in-market sales\*
- >> 500 000+ patients treated with Hexvix / Cysview worldwide

- NOK 1.7 billion Market cap\*\*
- 649K Avg daily volume YTD\*\*
- Oslo Stock
  Exchange:
  IPO May 2000



<sup>\*</sup> Total In Market Sales including US, Nordic and Partners
\*\* 06/05/2020

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



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

**C**ANCER (NMIBC)

9th most common cancer worldwide1

550,000

new cases1

200,000 deaths annually of which 75% are men1

COMMON

Bladder Tumor **EXPENSIVE** 

Tumor as seen

through a cystoscope

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

**USD 5.7 Billion** 

Cost of Bladder Cancer in the U.S., projection for 2020<sup>3</sup>

**RECURRING** 

61%

recurrence in 1 year4

recurrence in 5 years4

**PROGRESSING** 

2% - 50%

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

1. Globocan. Incidence/mortality by population. Available at: 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.

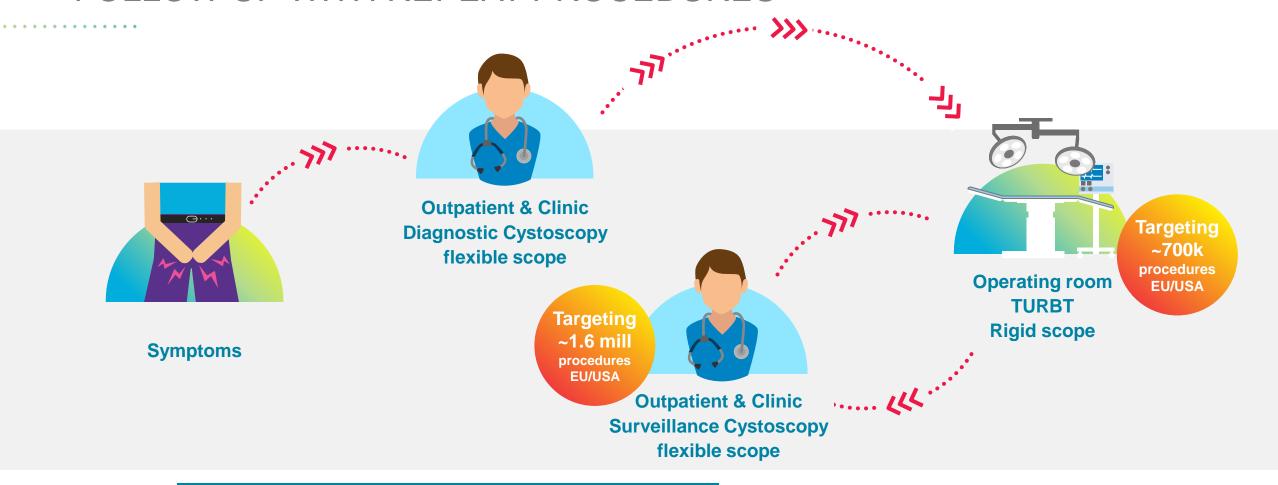
4. Sylvester RJ et al. Eur Urol 2006. Global Data: Bladder Cancer Report.

**DEBILITATING** 

Lifelong follow-up with repeat TURBTs and cystoscopies

Potential urinary dysfunction, patient fear, anxiety and confusion

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

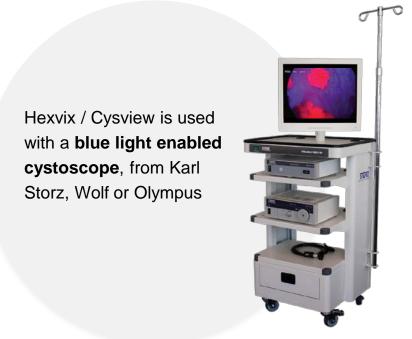


Hexvix®/Cysview®: Use for the 1st TURBT and for all intermediate and high-risk NMIBC patients during surgical treatment and surveillance / follow-up



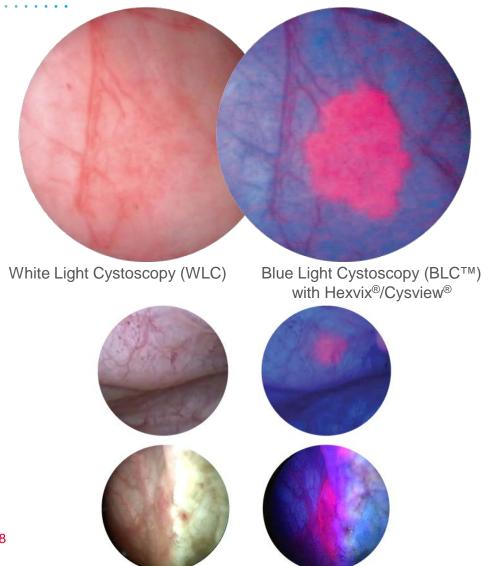
# HEXVIX®/CYSVIEW® FOR BETTER DETECTION AND MANAGEMENT OF NMIBC







# BLUE LIGHT CYSTOSCOPY: CREATING A NEW STANDARD OF CARE "YOU CANNOT TREAT WHAT YOU CANNOT SEE!"



- 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 mismanagement 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

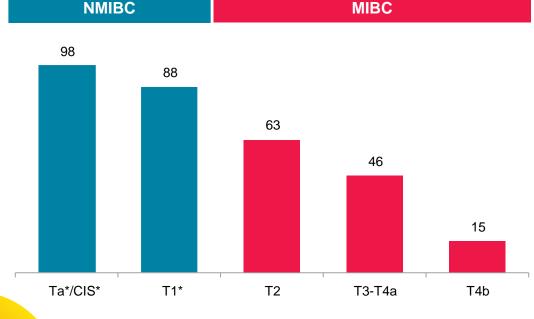


# BLUE LIGHT CYSTOSCOPY CAN PROVIDE AN ACCURATE AND COMPLETE 1ST TURBT – CRITICAL FOR PATIENT OUTCOMES

#### **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

#### 5-Year Relative Survival Rate (%)

Stage	Recurrence rate	Progression to MBIC
Low grade Ta	70%	2%
High-grade Ta	50-80%	14-48%
T1	70%	30-50%
CIS	43-73%	50%



<sup>\*</sup> Ta, T1, CIS: Non muscle invasive bladder cancer tumor types

Sources: All: Global Data: Bladder Cancer Report, Sylvester RJ et al. Eur Urol 2006

Note: 1) Stages from tumor growing into the perivesical tissue and until it has spread to the prostate, uterus or vagina; 2) The tumor has spread to the pelvic wall or the abdominal wall except

Q1 2020 Highlights and Financials

# 1<sup>ST</sup> QUARTER HIGHLIGHTS CONTRIBUTING TO PHOTOCURE STRATEGY IMPLEMENTATION

#### Regaining worldwide rights to Hexvix

Expected to be EBITDA<sup>1</sup> accretive from full-year 2021

#### Financial growth highlights:

- Positive growth rate in Q1, Hexvix/Cysview revenue growth of 6%
  - Some impact of Covid-19 during the last weeks of the quarter
- Q1 revenue growth YoY in U.S. was 21% in USD, driven by 17% growth in unit sales
  - US accounts for 52% of our total sales revenue
- Installed base of rigid and flex BLC +14 Rigid, +1 Flex
- Cost reduction initiatives to reduce impact of Covid-19

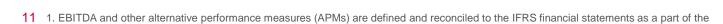
#### **Product highlights:**

- U.S. patent for neoadjuvant therapy for patients scheduled for cystectomy (Expiry 2036)
- Media traction for BLC (Fox News Channel 11 LA, January 2020)

#### **Partnership highlights:**

APM section of the fourth quarter 2019 financial report on pages 20-21

• Asieris payment of USD 1.5 million in Q1, according to license agreement







### SEGMENT PERFORMANCE FIRST QUARTER 2020

Amounts in NOK million	Q1 '20	Q1 '19	Change	FY '19
Commercial Franchise	Q(1 Z0	QT 13	Orlange	11 13
US revenue	28.2	21.2	33%	98.7
Nordic revenue	12.2	13.1	-7%	48.2
Partner revenue	14.0	17.0	-18%	66.3
Total Hexvix/Cysview	54.4	51.2	6%	213.2
Other revenue	0.3	1.0		3.2
Total revenue	54.7	52.2	5%	216.4
Operating expenses	-52.3	-45.1	16%	-186.6
EBITDA before restr.	-3.5	1.7		7.3
Development Portfolio				
Total revenue	0.3	-		65.1
Operating expenses	-1.3	-3.2	-59%	-13.5
EBITDA before restr.	-1.2	-3.2		51.6
TOTAL				
EBITDA before restr.	-4.8	-1.5		58.9

#### Commercial Franchise

- US: Strong revenue growth 33%. Growth in USD 21%, driven by unit sales and price
  - Impact of Covid-19 on unit sales from last two weeks of quarter
  - Installed base of rigid and flex BLC 238 at quarter end, increase of 15 units in the quarter. Increased 39% YOY
- Nordic: Q1 revenue decline 7%, mainly driven by reduced unit sales in Denmark due to stock up at hospitals end of 2019
- Partner: Revenue decline in Q1 18%. Largest driver is billing of COGS to partner (Ipsen)
- Increased operating expenses, Q1 at 16% YOY, sales and marketing programs in general and commercial investments in US. Significant currency impact in Q1, USD +10.6% YoY

#### Development Portfolio

Operating expenses Q1 reduced YOY 59%

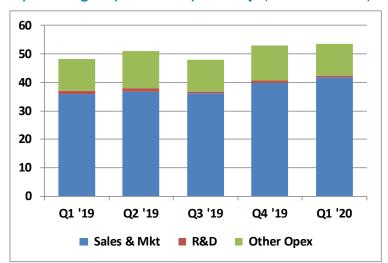


# CONSOLIDATED INCOME STATEMENT FIRST QUARTER 2020

Amounts in NOK million	Q1 '20	Q1 '19	Change	FY '19
Hexvix/Cysview revenue	54.4	51.2	6%	213.2
Other revenue	0.6	1.0		68.3
Total revenue	55.0	52.2	5%	281.6
<b>Gross profit</b>	48.8	46.8	4%	259.0
Operating expenses	-53.6	-48.3	11%	-200.1
EBITDA before restr.	-4.8	-1.5		58.9
Depreciation & Amort.	-3.9	-4.2		-16.2
EBIT before restr.	-8.6	-5.8		42.7
Restructuring expenses	-1.9	-		-
Net financial items	5.7	-0.2		3.2
Earnings before tax	-4.8	-6.0		45.9
Tax expenses	-12.9	1.0		-14.1
Net earnings	-17.7	-4.9		31.8

- Operating expenses, increase driven by
  - Significant FX impact, average approximately 8%
  - Planned investments in US commercial operations (sales & marketing) as well as program spending
- Restructuring expenses from work related to Ipsen agreement
- Net financial items driven by FX on receivables (Asieris license agreement)
- Tax expense, non cash: Net income in parent company due to FX drives release of tax asset. No tax payable

#### Operating expenses, quarterly (NOK million)





### CASH FLOW FIRST QUARTER 2020

Amounts in NOK million	Q1 '20	Q1 '19	FY '19
Operations cash flow	3.0	-15.7	20.7
Earnings before tax	-4.8	-6.0	45.9
Working capital	-6.6	-12.5	-7.1
Other	14.4	2.8	-18.2
Investments cash flow	-0.4	0.5	0.6
Development exp.	-0.3	-	-0.3
Other	-0.1	0.5	0.9
Financing cash flow	-0.4	-0.2	-2.8
Share capital	-	0.6	0.6
Other	-0.4	-0.9	-3.4
Net change in cash	2.2	-15.4	18.5
Ending cash balance	127.6	91.4	125.3

- Cash flow from operations Q1 improved mainly due to milestone payment of USD 1.5 million from Asieris as well as improved working capital
  - Other operations cash flow includes reduced receivable on Asieris as revenue was accounted for in 2019
- Cash flow from financing includes payment of lease liability totaling NOK 0.4 million in Q1
- Net change in cash at NOK 2.2 million, an improvement of NOK 17.6 million compared to last year
- Quarter end cash balance at NOK 127.6 million



### BALANCE SHEET 31 MARCH 2020

31.12 2019	31.12 2019
54.6	70.5
11.3	13.6
25.4	38.3
17.8	18.5
57.8	61.6
127.6	125.3
239.9	257.4
190.4	208.6
9.8	10.0
39.8	38.7
239.9	257.4
79%	81%
	2019 54.6 11.3 25.4 17.8 57.8 127.6 239.9 190.4 9.8 39.8 239.9

#### Non current assets

- Investments of NOK 11.3 million in tangible and intangible assets is driven by investments in Cysview phase 3 project. This project will be fully amortized in 2020
- Deferred tax asset of NOK 25.4 million. Reduced mainly due to foreign exchange movements in parent company
- 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 offset by payment of the short-term part of the Asieris receivable
- Long term liabilities include impact from adoption of IFRS 16 (Leases)
- No interest bearing debt
- Shareholder's equity of NOK 190.4 million. Equity ratio of 79%



## Expand and Acquire World Wide Rights to Hexvix

#### **KEY DEAL CONSTRUCTS**

- Agreement with Ipsen for the return of Hexvix® sales, marketing and distribution rights in Europe and other markets currently controlled by Ipsen
- Photocure will commence the commercial operations with Hexvix in Europe from 1 October 2020
  - Countries not currently partnered or commercialized by Ipsen will be returned to Photocure upon signing
- Photocure will pay Ipsen EUR 15 million in acquisition cost on the date of transfer
  - To be funded through equity issue and cash balance
  - Ipsen will book sales up until 30 September 2020. After transition Ipsen will receive earn-out payments in the range of 10-15% of sales (years 1-7) and 7.5% of sales (years 8-10) in the current Ipsen markets
- The costs associated with the return of Hexvix® sales, marketing and distribution rights in Europe and other markets currently controlled by Ipsen is to be financed through a combination of cash, debt and/or equity
  - Received offers from debt providers, and agreements on financing may be entered into to ensure completion of the settlement 1



#### PHOTOCURE UNLOCKS TREMENDOUS POTENTIAL IN EUROPE

#### **Strategic opportunity**

- Apply commercial success & strong growth in the Nordic and the U.S. markets to the European region
- Deep knowledge of our product and the disease state
  - Minimal learning curve needed
- Leveraging our international expertise
  - Expanding our global footprint
- Build a scalable business platform for future acquisitions and growth
- Building upon our credibility in the bladder cancer space

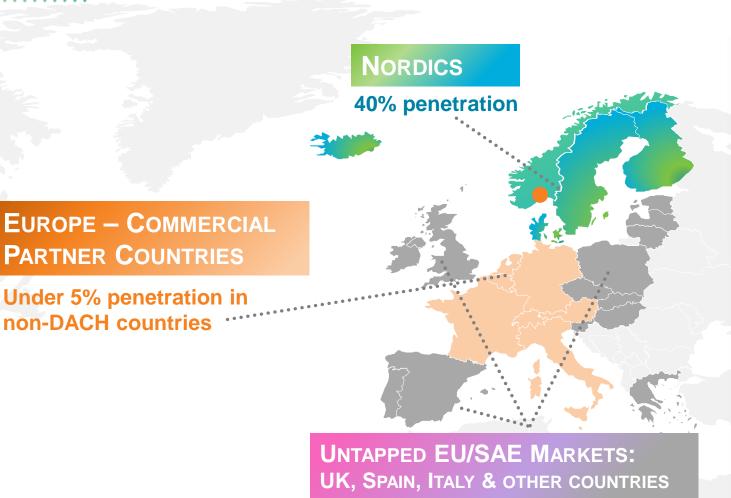
#### **Value-creation opportunity**

- After transition year targeting 20-30% annual revenue growth in current Ipsen territories
- Expected to be EBITDA<sup>1</sup> accretive from full-year 2021
- Current EU penetration (except DACH) is <5% –</li>
   Opportunity to reach Nordic penetration level of ~40%
- Focused EU investment maximizing revenue returns



### LARGE UNTAPPED POTENTIAL IN THE EUR 150 MILL EUROPEAN MARKET

(CURRENT EU PENETRATION (EXCEPT DACH) <5% WITH OPPORTUNITY TO REACH NORDIC LEVEL OF 40%)



~0% penetration

### **Europe**

Europe: 165,000 new cases and more than 50,000 deaths annually<sup>1</sup>

#### U.S.

US: 82,500 new cases and more than 18,000 deaths annually<sup>1</sup>

EU5: 360,000 TURBTs

Ave. Hexvix price ~

**EUR 415** 

Germany: 30% current penetration, >3,500 units per sales FTE, growing

Major markets like UK, Spain not pursued, very limited resources in Italy, France

US: 315,000 TURBTs

Ave. Hexvix price ~ **USD 1070** 

Penetration 5-10%

Growth rate in excess of 35% Y-o-Y

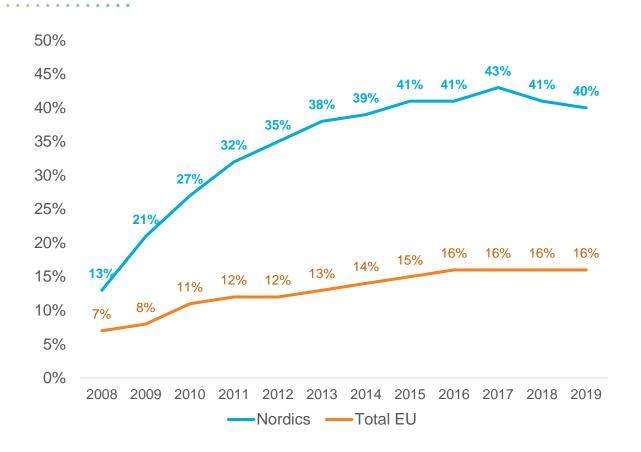
Increased commercial investment and focus delivering results

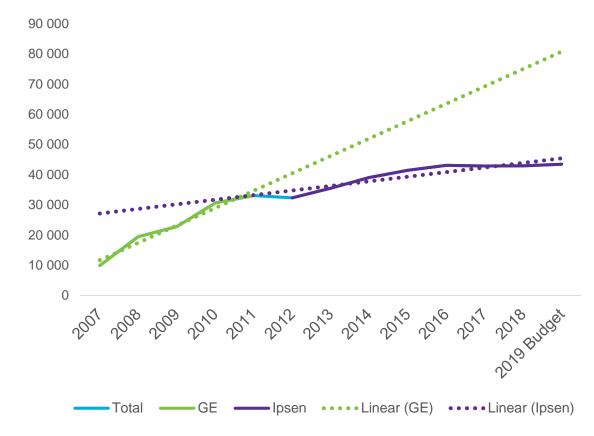
PARTNER COUNTRIES

**Under 5% penetration in** 

non-DACH countries

#### HISTORICAL FLAT TRENDLINES = SIGNIFICANT EU OPPORTUNITY!







Total EU is average market share based on TURB's in Major EU countries (GER, FRA, UK, ITA, AUS, NLD, BEL)

<sup>\*</sup> Ipsen signed contract on September 26th 2011
\*\* Linear Trend Ipsen from 2012 – 2018 Actuals

<sup>\*\*\*</sup> Linear Trend GE from 2007 – 2011 Actuals

#### SYNERGISTIC OPPORTUNITY LEVERAGING OUR INTERNAL EXPERTISE:

Organizatio

Get people in place with competencies and skills to address challenges and opportunities

EU General Manager recruited to lead initial organization of 20 FTEs

Supported by global functions with established training, medical and marketing programs and tools

Strategy

Drive use of Hexvix in existing clinics

Expand the number of clinics

Leverage Photocure's relationship with equipment suppliers

Increase KOL advocacy & engagement
Improve market access & reimbursement
Build strong Patient Advocacy relationships as in U.S.

Scalability

Leverage infrastructure, synergies, global approach and consistent global brand

Implement Best practices

Leverage investment in U.S. marketing and medical – scalable into global platforms

Culture and E

Accelerate / Expand / Acquire / Transform:

Establish global bladder cancer footprint in line with our strategy

Ambitions – driving change in our area of expertise

Continuity – dedicated team and performance-based culture



## Positioned for growth

### **US: ACCELERATED MOMENTUM**



**US (1000 NOK)** 



# U.S. ACCELERATED MOMENTUM: RECENT 8 QUARTERS' INSTALLATION FUELS FUTURE GROWTH!

#### **Annual New Installations**



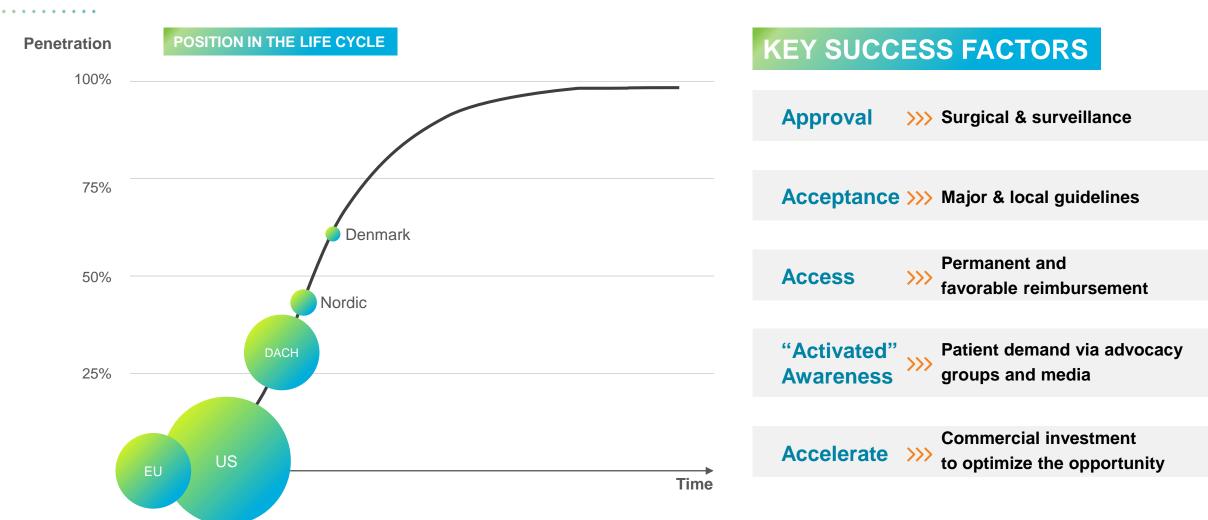
Tower placements by year

#### Cumulative install base continues strong trend





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





### **GLOBAL: SUPPORTIVE ENVIRONMENT & AWARENESS**

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

• Inclusion in Bladder Cancer treatment guidelines

BLCTM with Heyviv® (Cysview® is strongly recommended by

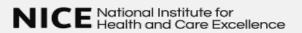
American Urological Association













- 80% adoption rate in top Cancer centers and growing 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
- Partnering with prominent Patient Associations
   especially BCAN in the US and the new World Bladder Cancer Patient Coalition





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

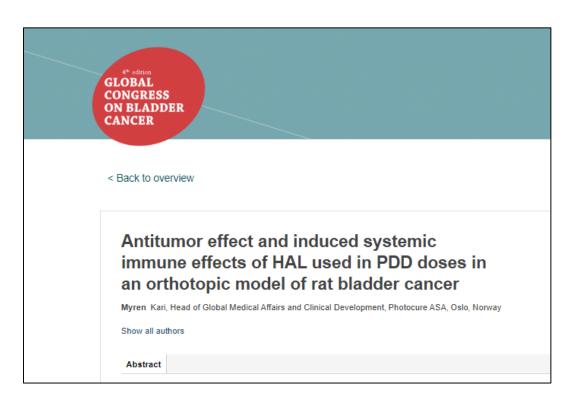
>>> Recent early stage studies show a potential treatment effect of Blue Light Cystoscopy (BLC<sup>TM</sup>) with Hexvix<sup>1</sup>

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 Protection Strategy

#### DRUG-DEVICE COMBINATION – HURDLES TO MARKET ENTRY

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

IP\*/Intellectual Property

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

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

Regulatory hurdles

A drug-device combination product. ANDA¹ for drug, PMA² 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

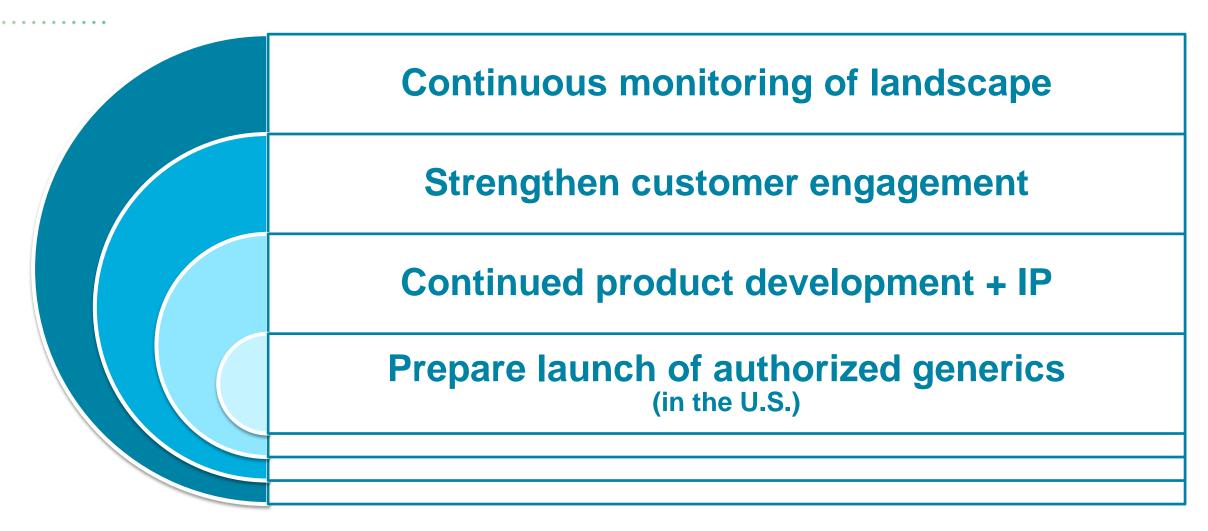
Active product support incl. training of physicians and nurses, facilitate workflow

Desk research/Market size

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

\* European patent expired September 2019, US patent valid until November 2020, Data exclusivity on flex valid until February 2021 PDT patent in the US granted until December 2036, Additional patents pending

## 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 has received a total signing fee of USD 5 million in 2019
- 1st milestone payment of USD 1.5 million in Q1 2020
- Approval of the initial indication will result in total 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 16 million
- Sales royalties and milestones will apply in all markets









BLC<sup>TM</sup> with Hexvix<sup>®</sup>/Cysview<sup>®</sup> can play an integral part in this situation: postponed procedures\* do not postpone aggressive cancer progression

- Patient safety through better detection of bladder cancer tumors, in spite of the potential longer check-up intervals during the COVID-19 crisis
- Low and medium-risk patient categories in particular could be treated in the office/flex setting:
  - less restrictive for the patients
  - performing flexible Blue Light Cystoscopies in the office setting frees up hospital capacity
- Less recurrence and avoiding progression to muscle-invasive bladder cancer stages
- The ministry of health in several countries urging hospitals to start addressing the backlog of procedures and surgeries as soon as possible



Centers of Excellence

Transformative Eviden

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Clinical Trials

<u>UroToday Home</u> > Library Resources > <u>Bladder Cancer</u>

### Risks of Delaying Bladder Cancer Diagnosis- Surveillance and Surgery During COVID-19

The rapid spread of Coronavirus Disease 2019 (COVID-19), caused by the betacoronavirus SARS-CoV-2, throughout the world has had dramatic effects on healthcare systems with impacts far beyond the patients actually infected with COVID-19.

Patients who manifest severe forms of COVID-19 requiring respiratory support typically require this for prolonged durations, with a mean of 13 days of respiratory support reported by the China Medical Treatment Expert Group for COVID-19.<sup>1</sup> This lengthy requirement for ventilator support and ICU resources, exacerbated by relatively little excess health system capacity to accommodate epidemics, means that healthcare systems can (and have in the case of many hospitals in Italy) become overwhelmed relatively quickly. In an effort to conserve hospital resources, the American College of Surgeons on March 13<sup>th</sup> recommended that health systems, hospitals, and surgeons should attempt to



#### **GUIDANCE: APPROXIMATELY 1BN REVENUE IN 2023**

### Current-year guidance:

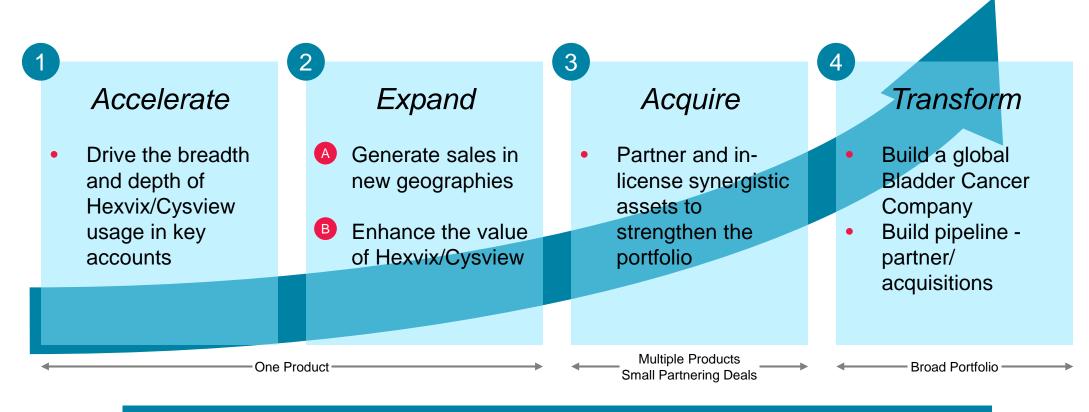
- Q1 revenue growth YoY in U.S. at 21% in USD, driven by 17% growth in unit sales
- Near term temporary pressure on revenue due to COVID-19 impact
- Rebound in H2: steady return expected

### 2023 guidance:

- Group revenues ambitions in the range of NOK 1 billion
- EBITDA margins approximately 40%



### CREATING THE LEADING BLADDER CANCER COMPANY



Ambition of world wide revenues in range of NOK 1 Billion in 2023 and approximate 40% EBITDA margin in 2023



Q&A