

PHOTOCURE – COMPANY UPDATE

27 April 2020

Daniel Schneider, President and CEO
Erik Dahl, CFO



THE
BLADDER CANCER
COMPANY™

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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

HEXVIX®
Hexaminolevulinate 85mg

CYSVIEW®
Hexaminolevulinate HCl

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 1.5 billion** Market cap**
- » **650K** Avg daily volume YTD**
- » Oslo Stock Exchange: **IPO May 2000**

* Total In Market Sales including US, Nordic and Partners

** 24/04/2020



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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**

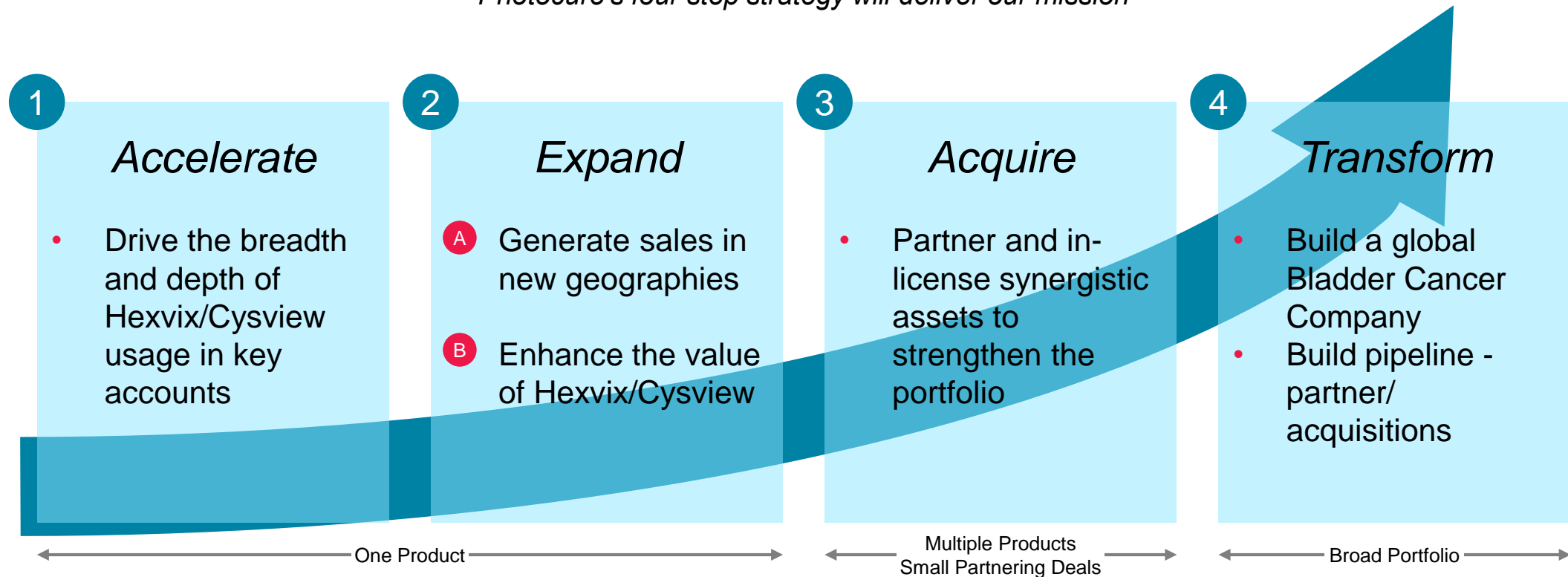
2020 + beyond



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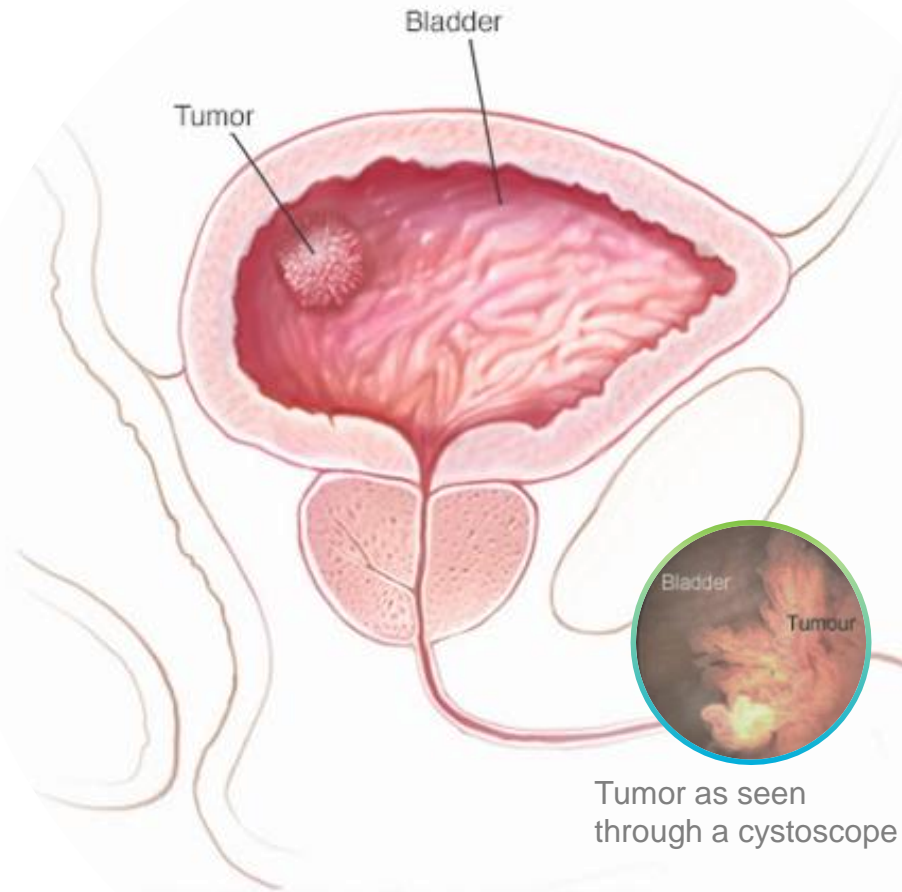
OUR MISSION IS TO DELIVER TRANSFORMATIVE SOLUTIONS WHICH IMPROVE THE LIVES OF BLADDER CANCER PATIENTS

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)



Tumor as seen
through a cystoscope

COMMON

9th

most common
cancer worldwide¹

550,000
new cases¹

200,000
deaths annually
of which 75% are men¹

EXPENSIVE

#1

Highest per patient
lifetime treatment costs
of any cancer²

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

RECURRING

61%
recurrence
in 1 year⁴

78%
recurrence
in 5 years⁴

PROGRESSING

2% – 50%

Disease progression from NMIBC to MIBC⁴

DEBILITATING

» Lifelong follow-up
with repeat TURBTs and cystoscopies

» Potential urinary dysfunction, patient fear,
anxiety and confusion

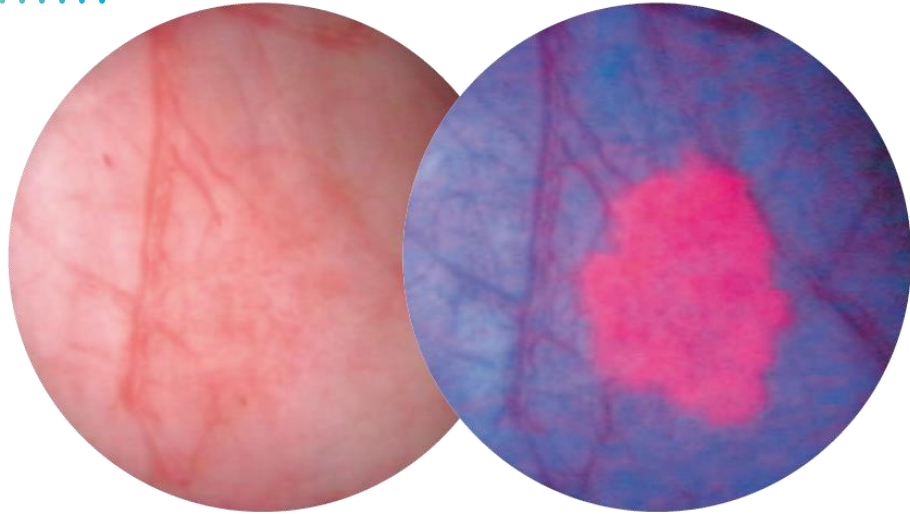
1. Globocan. Incidence/mortality by population. Available at: http://globocan.iarc.fr/Pages/bar_pop_sel.aspx

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.

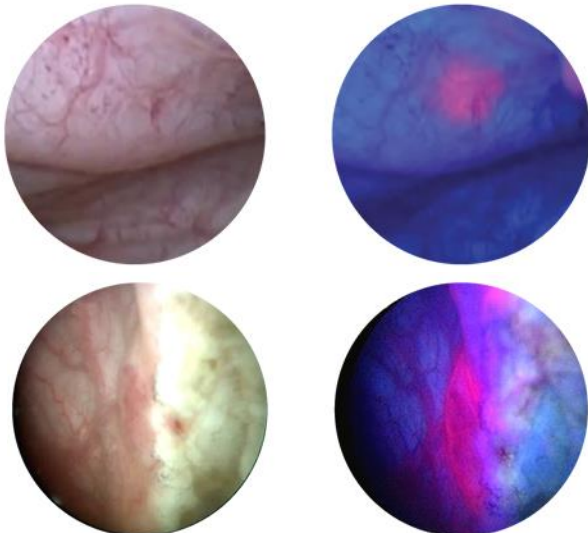
4. Sylvester RJ et al. Eur Urol 2006, Global Data: Bladder Cancer Report,

“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^{1,2}



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

*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

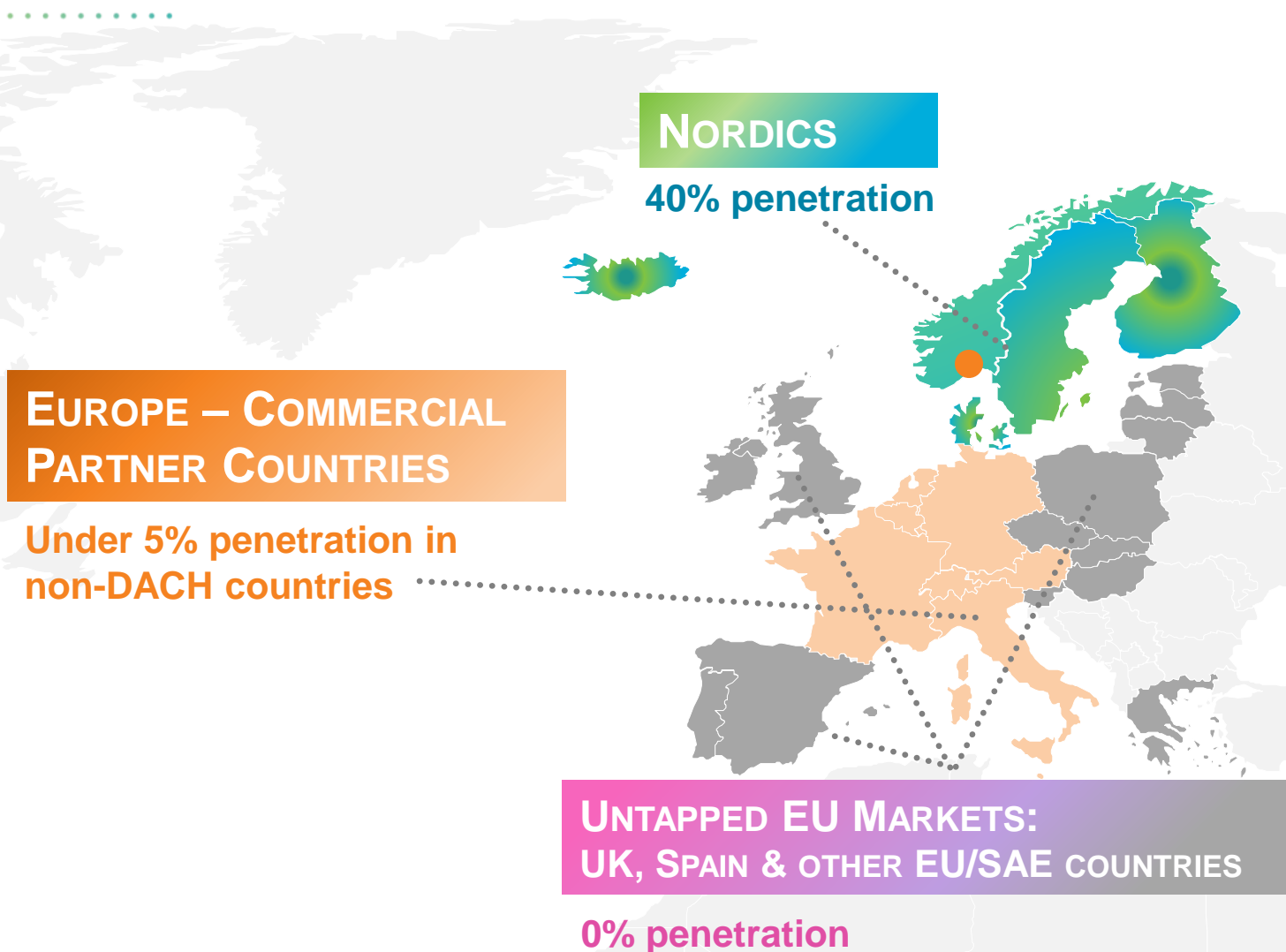
Value-creation opportunity

- After transition year targeting 20-30% annual revenue growth in current Ipsen territories
- Revenue in the range of NOK 1 billion (2023)
- Expected to be EBITDA¹ accretive from full-year 2021
- EBITDA margin approximately 40% (2023)
- Current EU penetration (except DACH) is <5% – Opportunity to reach Nordic penetration level of 40%
- Focused EU investment maximizing revenue returns

11 1. EBITDA and other alternative performance measures (APMs) are defined and reconciled to the IFRS financial statements as a part of the APM section of the fourth quarter 2019 financial report on pages 20-21

LARGE UNTAPPED POTENTIAL IN THE EUR 150 MILL EUROPEAN MARKET

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



Europe

Europe: 165,000 new cases, 550,000 prevalent cases, and more than 50,000 deaths annually¹

EU5: 360,000 TURBTs

Ave. Hexvix price ~ 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

U.S.

US: 82,500 new cases, 280,000 prevalent cases, and more than 18,000 deaths annually¹

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

SYNERGISTIC OPPORTUNITY LEVERAGING OUR INTERNAL EXPERTISE:

Organization

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 ambitions

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



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Q1 update and guidance



1ST QUARTER HIGHLIGHTS CONTRIBUTING TO PHOTOCURE STRATEGY IMPLEMENTATION

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

Partnership highlights:

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



Product highlights:

- U.S. patent for neoadjuvant therapy for patients scheduled for cystectomy (Expiry 2036)
- Traction for the procedure on regional Fox News channel: Fox 11 LA program in January 2020 on Blue Light Technology in Bladder Cancer



COVID-19 ORGANIZATION RESPONSE

- Transparency: Informing the markets early on (for details, see Market Update #2, April 7, 2020)
- Market & Demand situation: Bladder cancer treatments are prioritized procedures but there are short-term postponements of procedures
- Priority on the health and welfare of all Photocure employees and stakeholders: remote work arrangements & travel policies across locations/functions
- Financial situation: Cost saving measures taken during Q2 to counteract COVID-19 impact
- Uninterrupted supply chain: production & inventory satisfactory
- Outlook: Experiencing some COVID-19 impact in the short-term but long-term outlook remains strong
- Continuing to update the markets as the situation evolves



OPTIMISTIC TO REBOUND FROM COVID-19 IMPACT IN H2

BLC™ with Hexvix®/Cysview® 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



[UroToday Home](#) > [Library Resources](#) > [Bladder Cancer](#)

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-19.¹ 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 13th recommended that health systems, hospitals, and surgeons should attempt to

SEGMENT PERFORMANCE

FIRST QUARTER 2020

<i>Amounts in NOK million</i>	Q1 '20	Q1 '19	Change	FY '19
Commercial Franchise				
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	-54.0	-45.1	20%	-186.6
EBITDA	-5.2	1.7		7.3
Development Portfolio				
Total revenue	0.3	-		65.1
Operating expenses	-1.5	-3.2	-53%	-13.5
EBITDA	-1.4	-3.2		51.6
TOTAL				
EBITDA	-6.7	-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, and 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 20% YOY, sales and marketing programs in general and commercial investments in US

Development Portfolio

- Operating expenses Q1 reduced YOY 53%

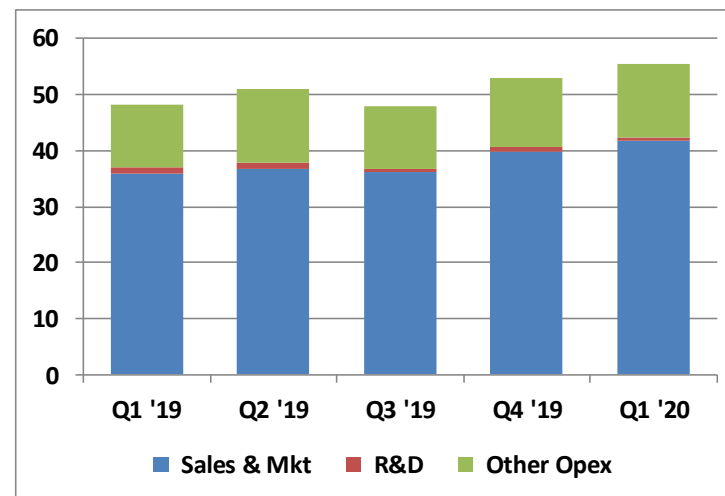
CONSOLIDATED INCOME STATEMENT & CASH POSITION

FIRST QUARTER 2020

<i>Amounts in NOK million</i>	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
Gross profit	48.8	46.8	4%	259.0
Operating expenses	-55.5	-48.3	15%	-200.1
EBITDA	-6.7	-1.5		58.9
Depreciation & Amort.	-3.9	-4.2		-16.2
EBIT	-10.5	-5.8		42.7
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
 Net change in cash	 2.2	 -15.4		 18.5
Ending cash balance	127.6	91.4		125.3

- **Operating expenses**, increase driven by
 - Planned investments in US commercial operations (sales & marketing) as well as program spending
 - Significant FX impact, approximately 8%
- **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
- **Strong cash position**, NOK 128 million at quarter end
 - Net inflow NOK 2.2 in Q1, including USD 1.5 million from Asieris

Operating expenses, quarterly (NOK million)



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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%

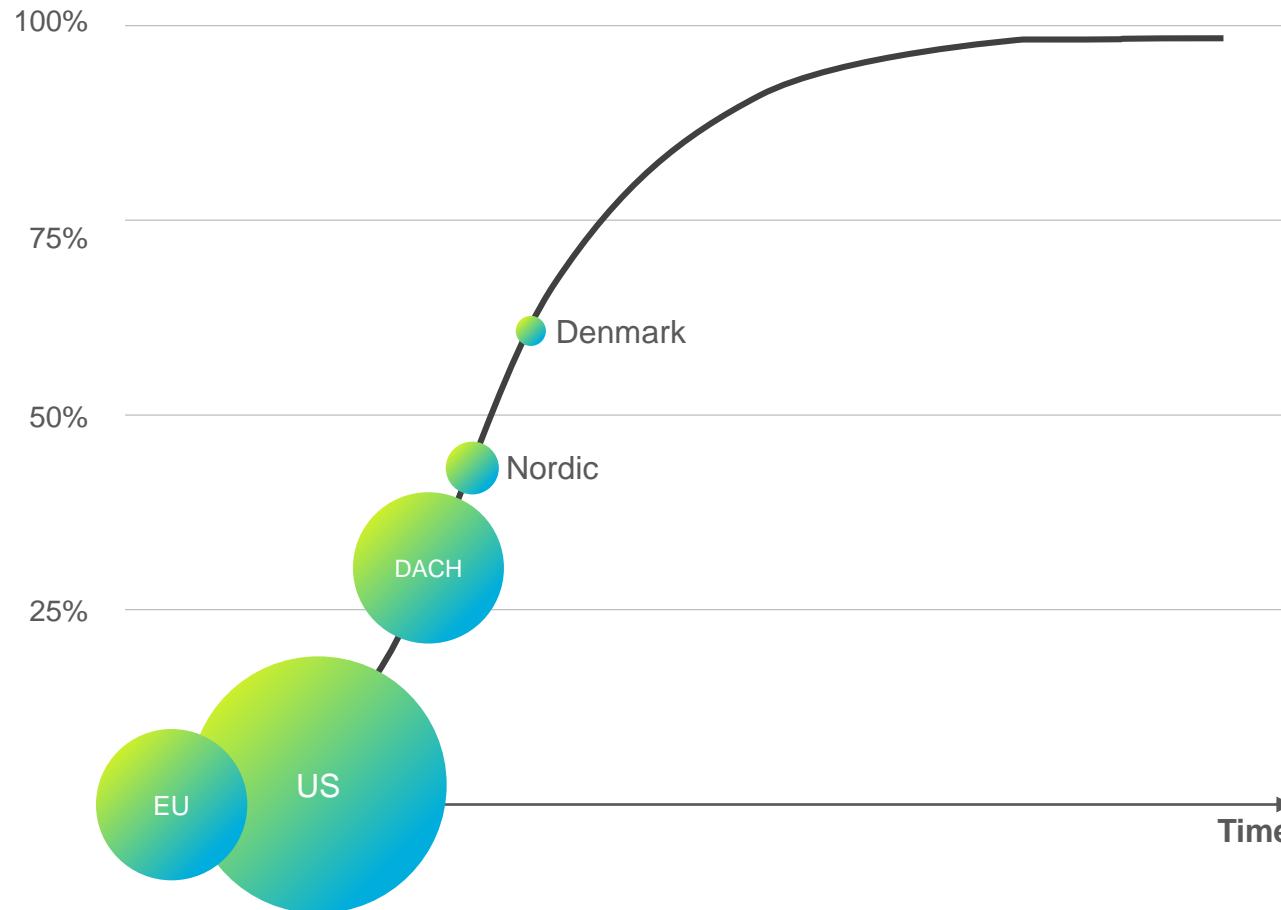
Positioned for growth



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



European
Association
of Urology

NICE National Institute for
Health and Care Excellence

- **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**

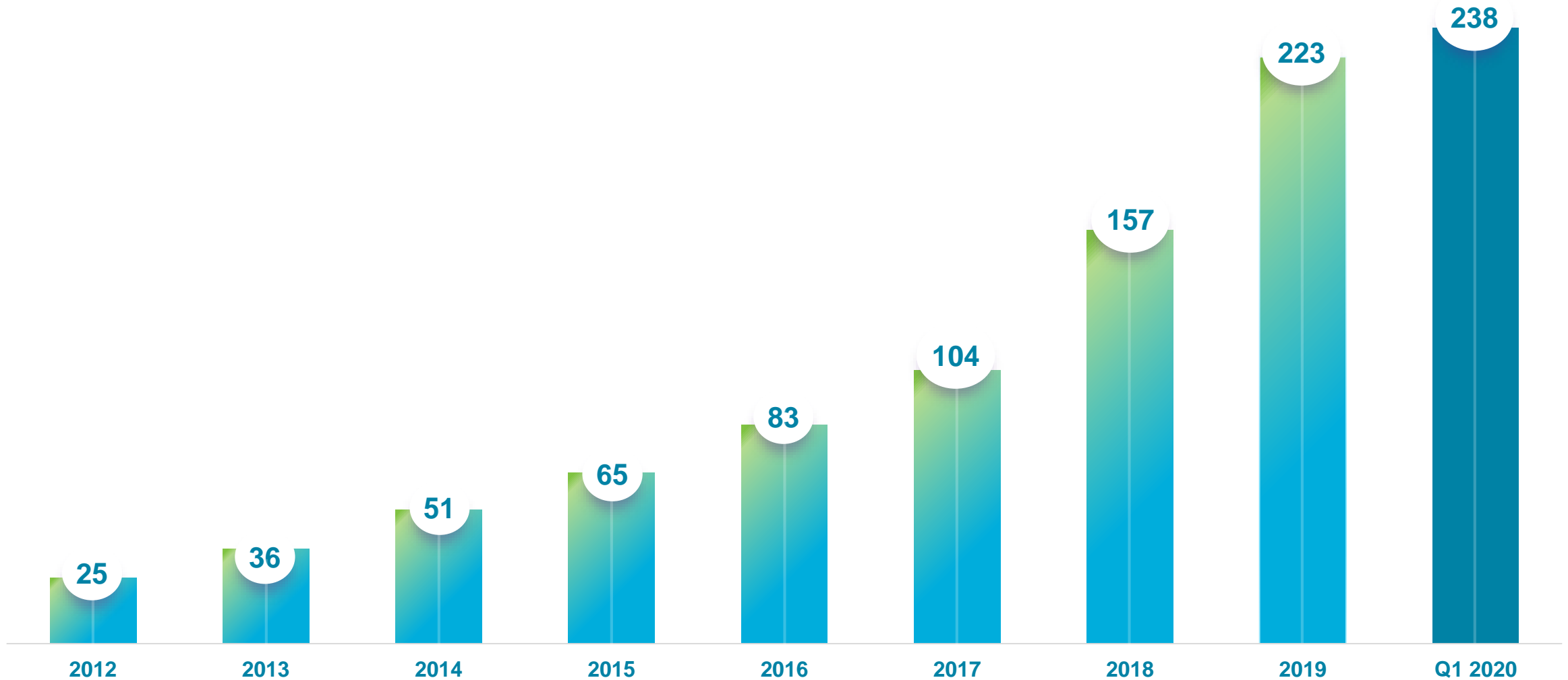
- **Partnering with prominent Patient Associations**

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



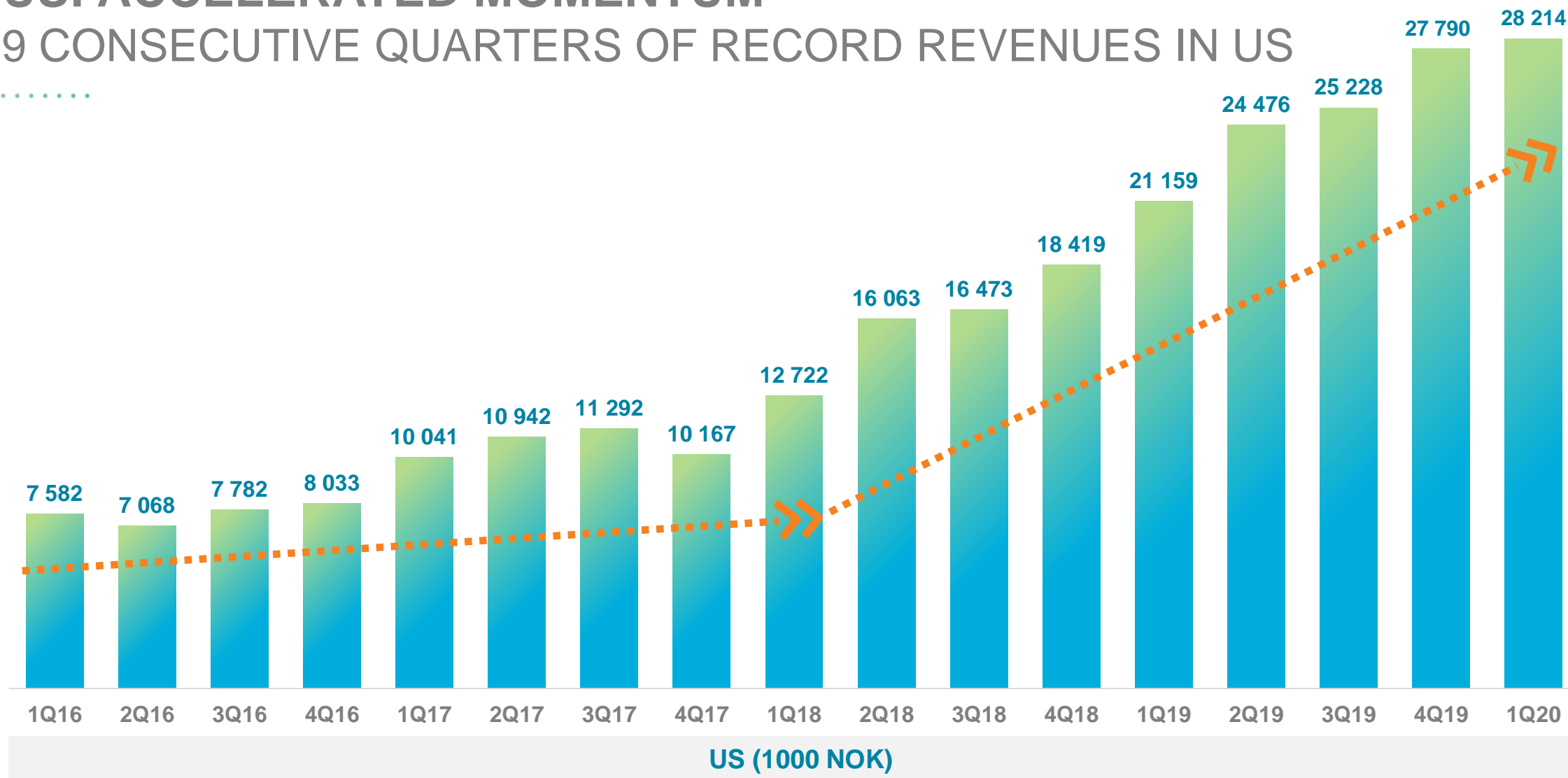
US: ACCELERATED MOMENTUM

INSTALLED BASE OF CYSTOSCOPES IN THE US



US: ACCELERATED MOMENTUM

9 CONSECUTIVE QUARTERS OF RECORD REVENUES IN 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 Hexvix¹

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 11th 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. 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

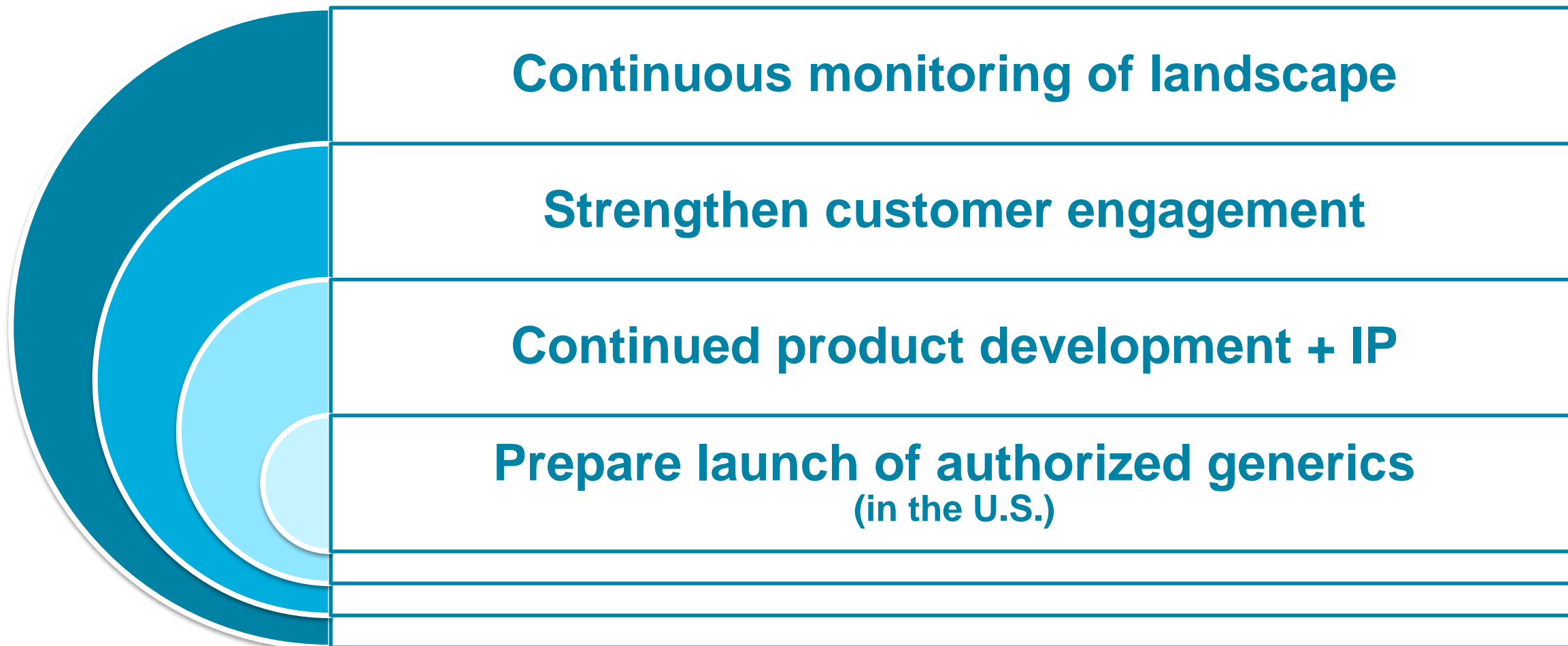
5

Commercial challenges

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

* 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

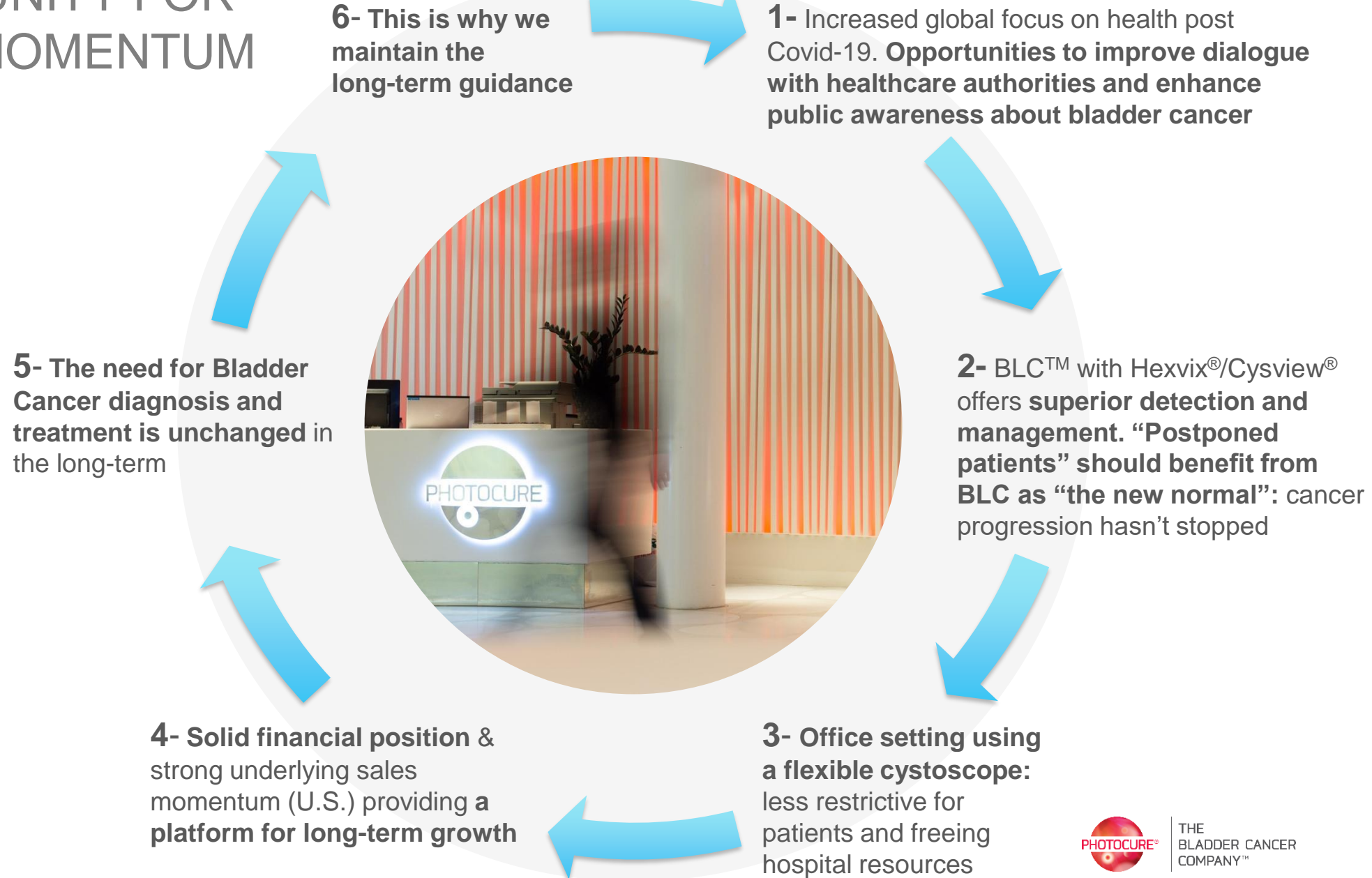
License Agreement terms: USD 250 mill potential in total:

- » 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 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

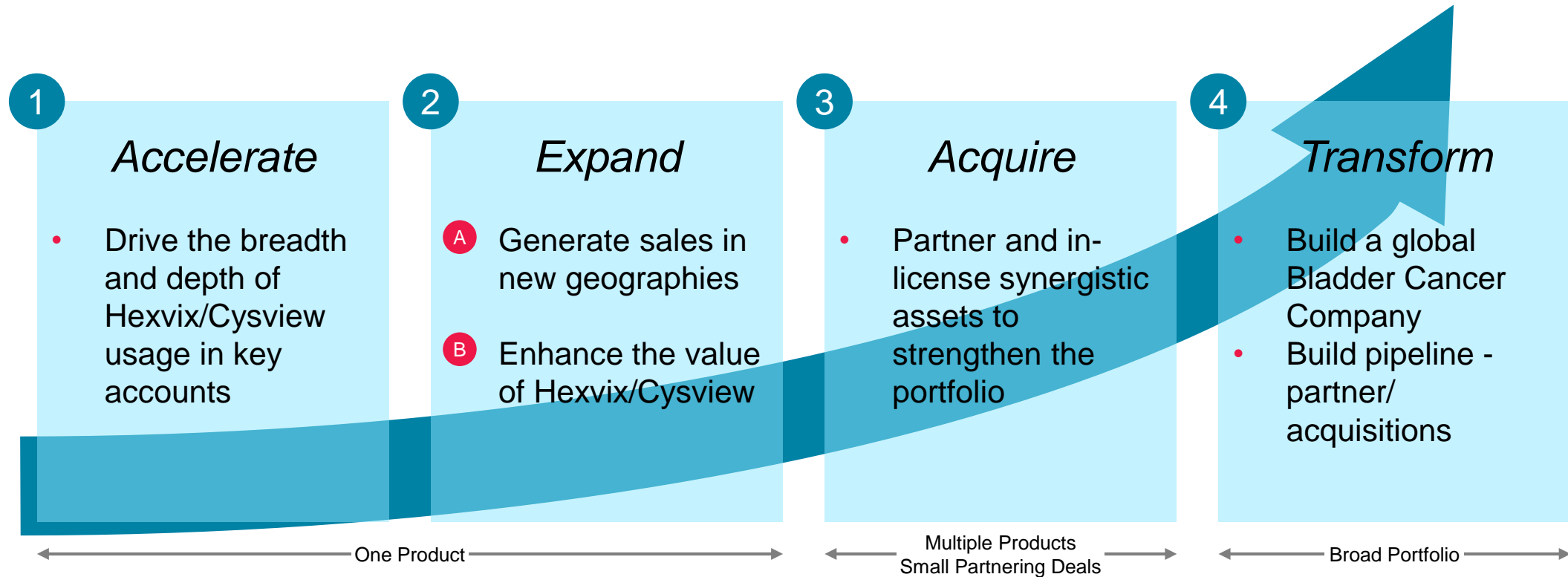
Summary and outlook



OUR OPPORTUNITY FOR INCREASING MOMENTUM



CREATING THE LEADING BLADDER CANCER COMPANY

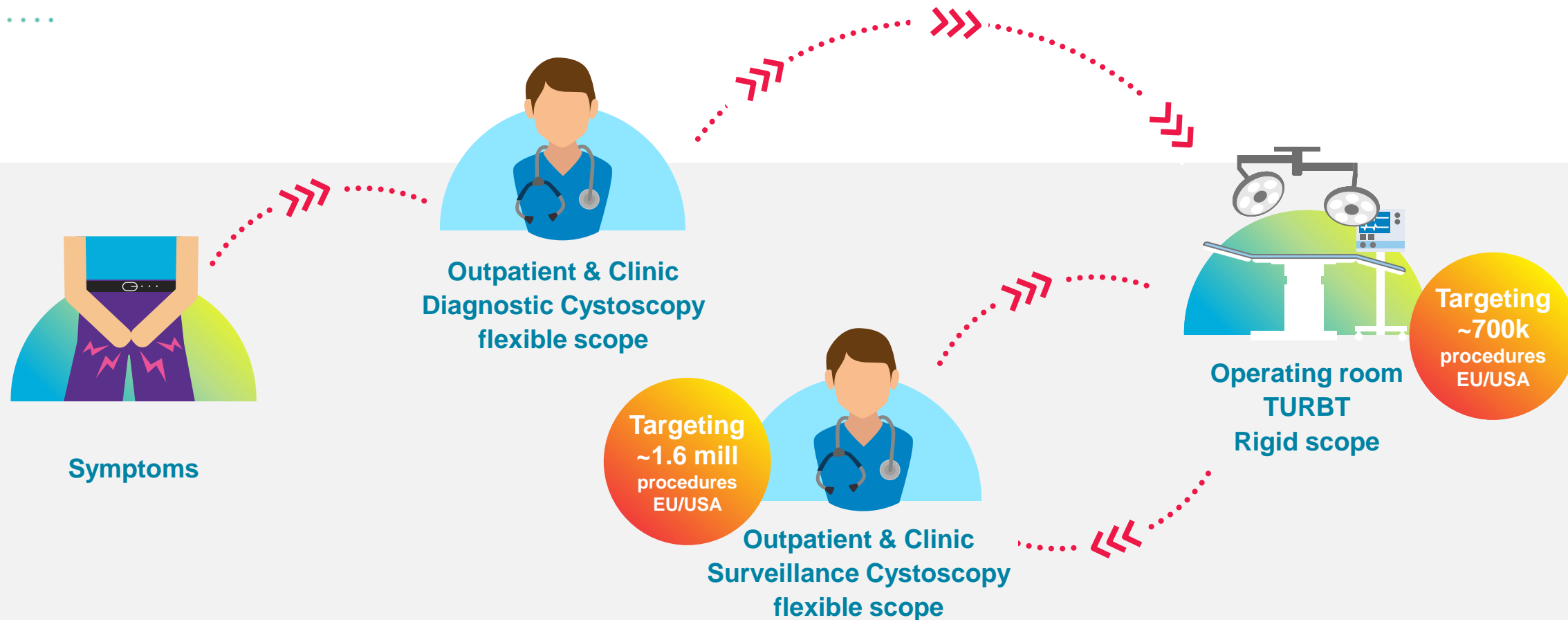


Ambition of world wide revenues in range of NOK 1 Billion in 2023

Q&A



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

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



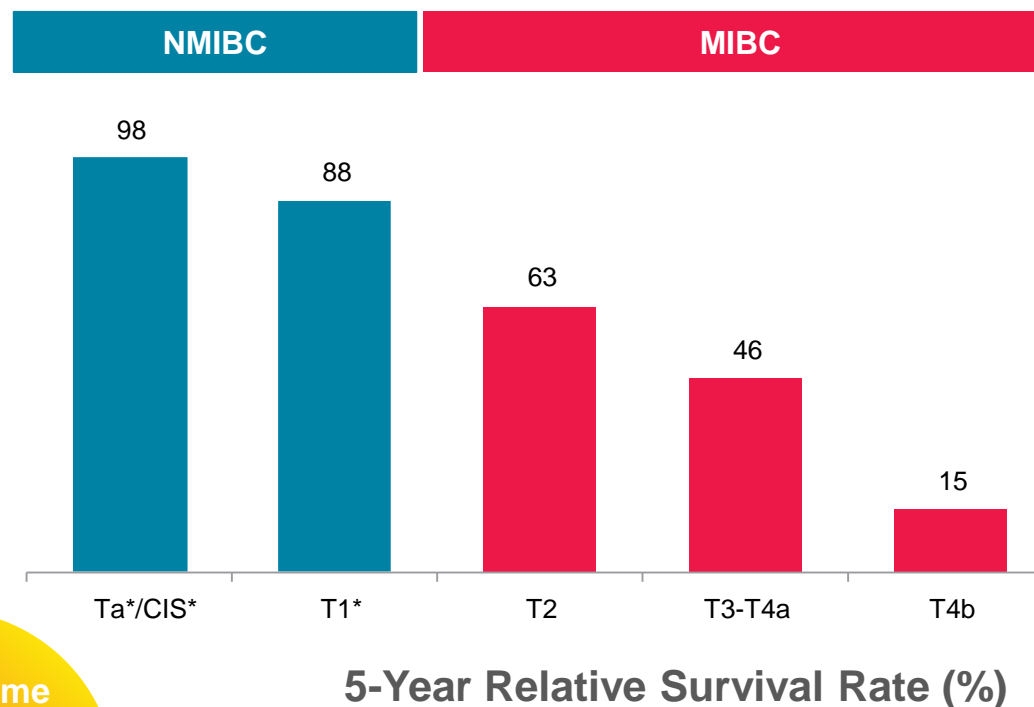
BLUE LIGHT CYSTOSCOPY CAN PROVIDE AN ACCURATE AND COMPLETE 1ST TURBT – CRITICAL FOR PATIENT OUTCOMES

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.²
- » 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