Photocure ASA
Results for 3rd quarter 2020

10 November 2020

Daniel Schneider, President and CEO

Erik Dahl, CFO

PHOTOCURE®

THE BLADDER CANCER COMPANY

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Thousands of bladder cancer patients across the world have received our breakthrough product

- Photocure Marketing Authorization
- Partner for Marketing Authorization
- Partner - Marketing Authorization in process

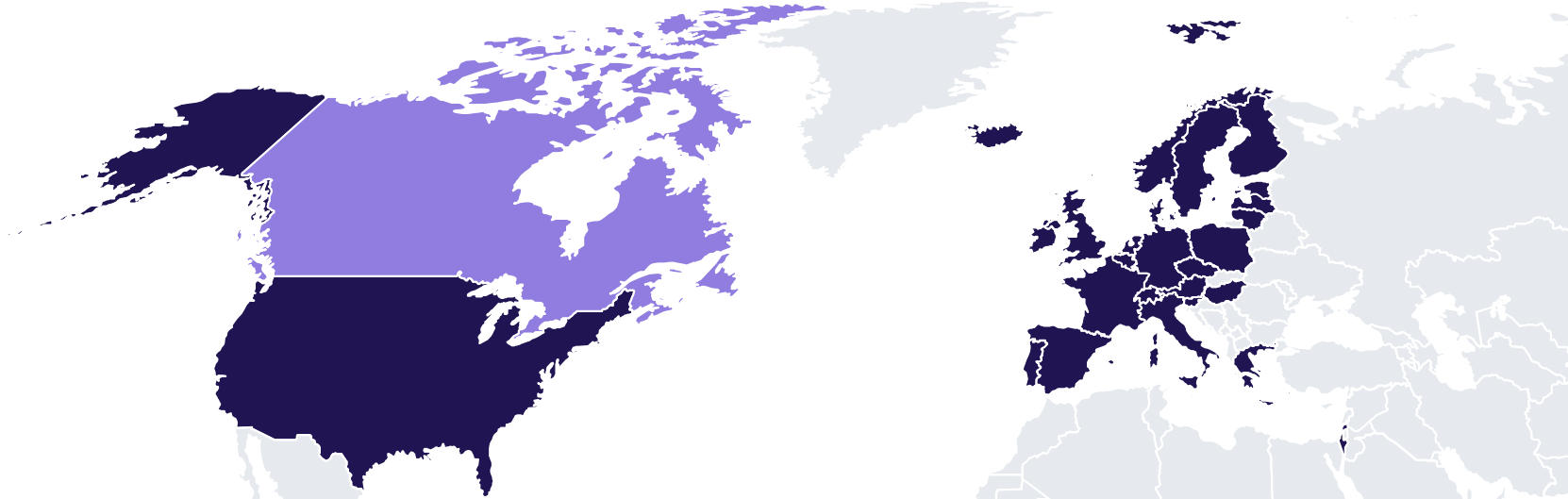
Direct sales in **U.S. & Europe** with worldwide partnerships

$32M total company revenue 2019

Approved for use in **~30 countries**

~100 employees

>500K patients



HEXVIX® Hexaminolevulinate 85mg

CYSVIEW® Hexaminolevulinate HCl

Hexvix Summary of product characteristics: https://www.hexvix.com/safety-information / **Cysview prescribing information:** https://packageinsert.s3.us-east-2.amazonaws.com/Cysview+PI+2020.pdf

Our Mission: Delivering transformative solutions to improve the lives of bladder cancer patients

PHOTOCURE® THE BLADDER CANCER COMPANY

Photocure's four step strategy to deliver on our mission & vision

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

Highlights in the 3rd quarter:

PHOTOCURE® THE BLADDER CANCER COMPANY

+17%
U.S. unit sales growth

+14%
Hexvix/Cysview Revenue Growth (adjusted)

European operations live on 1 October

Partnership news:
Cevira NMPA approval to start P3 in China
Genotests: Hexvix in Chile

HEXVIX® Hexaminolevulinate 85mg | CYSVIEW® Hexaminolevulinate HCl

Bladder cancer has been chronically underserved

PHOTOCURE® THE BLADDER CANCER COMPANY

COMMON (6th most common cancer worldwide[1])

550K new cases annually[1]

200K deaths annually of which 75% are men[1]

EXPENSIVE

Highest per patient lifetime treatment costs of any cancer[2]

USD 5.7B Cost of Bladder Cancer in the U.S., projection for 2020[3]

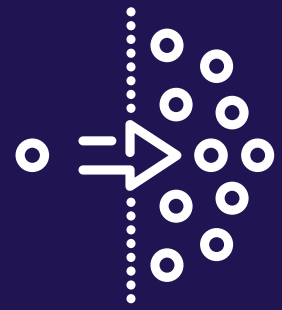
RECURRENT

Up to **61%** Recurrence in 1 year[4]

Up to **78%** Recurrence in 5 years[4]

PROGRESSIVE (FROM NMIBC TO MIBC, at 5 years)[4]

1%



45%

1) Globocan. Incidence/mortality by population. Available at: https://gco.iarc.fr/today, accessed [December 2019]. 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; 49:466-467 Global Data: Bladder Cancer Report

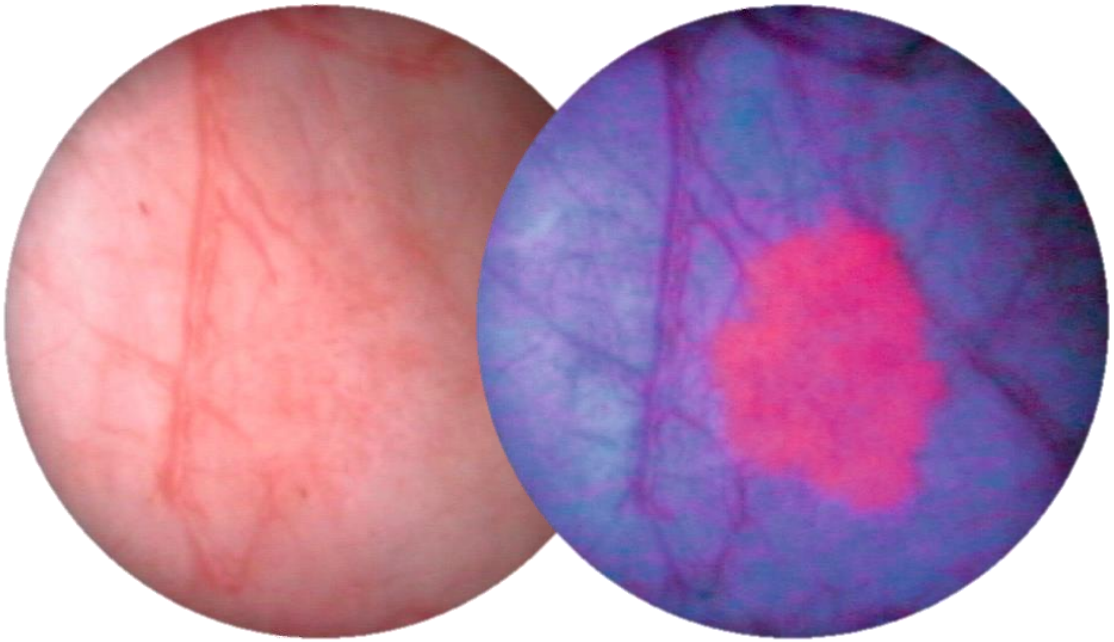
Blue Light Cystoscopy: Creating a New Standard of Care "You cannot treat what you cannot see!"

PHOTOCURE® THE BLADDER CANCER COMPANY

Improved detection vs. white light cystoscopy alone[1–4]

- Hexvix®/Cysview® is a drug that preferentially accumulates in bladder cancer cells, making them glow bright pink during blue light cystoscopy[5]
- Hexvix blue light cystoscopy offers improved detection during surgery and surveillance leading to a reduced risk of recurrence vs. white light cystoscopy alone[1–4,6–9]

HEXVIX® Hexaminolevulinate 85mg | CYSVIEW® Hexaminolevulinate HCl



Bladder cancer seen under white light (left) and using Hexvix®/Cysview® blue light cystoscopy® (right) - Courtesy of Professor Dirk Zaak; Traunstein, Germany.

Summary of product characteristics: https://www.hexvix.com/safety-information / **Cysview prescribing information:** https://packageinsert.s3.us-east-2.amazonaws.com/Cysview+PI+2020.pdf

References: 1. Hermann GG et al. *BJU Int* 2011; 108(8 Pt 2):E297–E303. **2.** Daneshmand S et al. *J Urol* 2018; 199(5):1158–1165. **3.** Stenzl A et al. *J Urol* 2010; 184(5):1907–1913. **4.** Burger M et al. *Eur Urol* 2013; 64(5):846–854. **5.** Hexvix® (hexaminolevulinate hydrochloride) 85 mg Summary of Product Characteristics. 2019. **6.** Drejer D et al. *Urology* 2020; 137:91–96. **7.** Gallagher KM et al. *World J Urol* 2017; 35(12):1871–1877. **8.** Geavlete B et al. *BJU Int* 2012; 109(4):549–556. **9.** Grossman HB et al. *J Urol* 2012; 188(1):58–62.

Supportive environment for becoming the standard of care for the detection & management of bladder cancer

Recommended in global & national guidelines:

American Urological Association

European Association of Urology

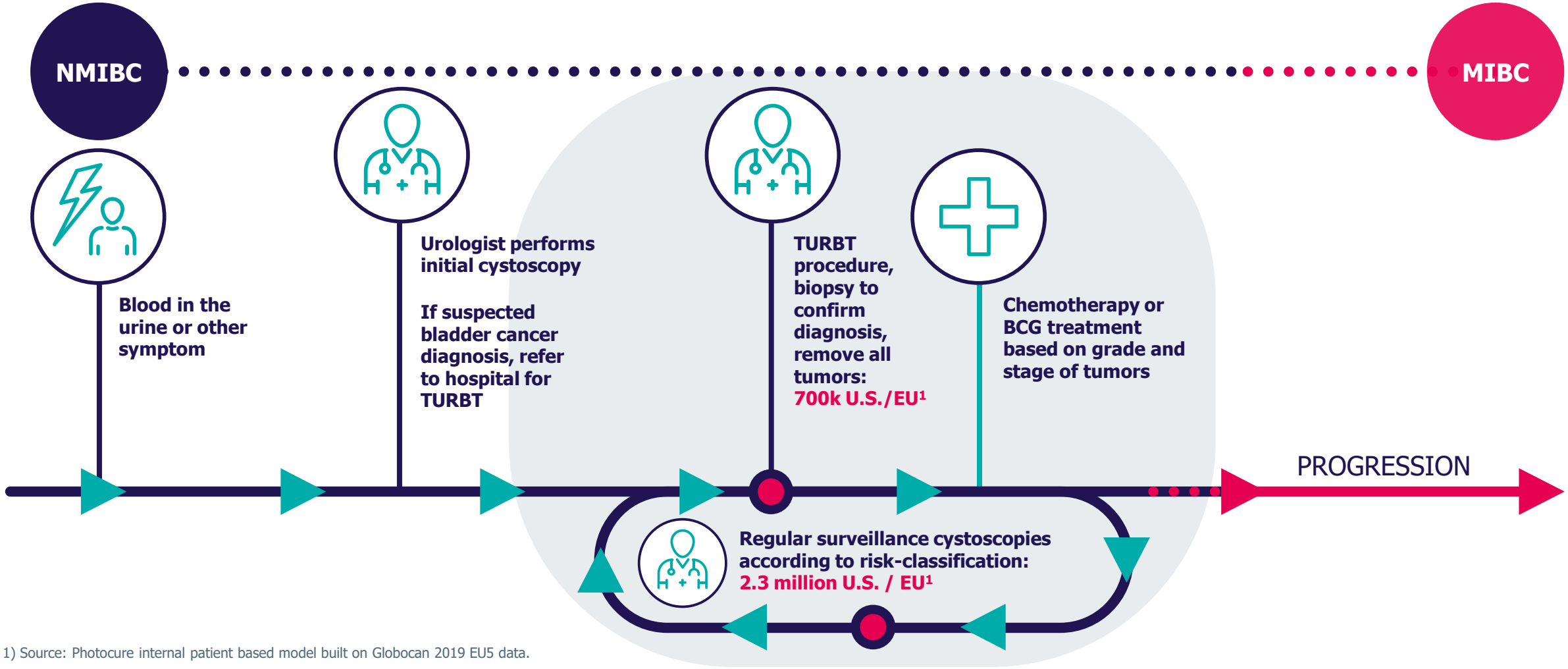
SUO Society of Urologic Oncology, Inc.

NICE National Institute for Health and Care Excellence

AFU Association Française d'Urologie

Deutsche Gesellschaft für Urologie e.V.

The Patient Journey: Characterized by long term follow-up with repeat procedures



1) Source: Photocure internal patient based model built on Globocan 2019 EU5 data.

Q3 2020 Financials

Q3 Financial Highlights - Strong Development Negatively Impacted by one-off Transition Costs

Amounts in NOK million	Reported Q3 '20	Transition Impact *	Adjusted Q3 '20	Q3 '19
Unit Sales ('000)	16.9k	-	16.9k	15.8k
Hexvix/Cysview Rev.	49.6	8.9	58.5	51.1
Total Revenue	**49.9**	**8.9**	**58.8**	**60.8**
Cost of Goods Sold	-3.5	2.5	-6.0	-4.7
Operating Expenses	-51.9	-1.5	-50.4	-47.8
EBITDA before Restr.	**-5.4**	**7.9**	**2.5**	**8.3**
Restructuring Exp.	-7.2	-7.2	-	-
Earnings before Tax	**-14.2**	**15.1**	**0.9**	**5.3**

* Impact of Q3 Transition Activities in Europe

Strong Sales Development in Key Markets

- U.S. volume growth 17%
- Europe volume growth 7%
- Hexvix/Cysview revenue growth (adjusted) 14%

Successful Transition and Launch in Europe

- Transition impact on EBITDA NOK -7.9 million. Adjusted EBITDA NOK 2.5 million
  - Return of inventory from Ipsen NOK 4.8 million
  - Reduced purchase by Ipsen NOK 4.1 million
  - Operating expenses related to transition NOK 1.5 million
- Total impact on earnings before tax NOK 15.1 million
  - Restructuring expenses NOK 7.2 million

Segment Performance

Third Quarter 2020

Amounts in NOK million	Q3 '20	Q3 '19	Change	YTD '20	YTD '19	Change
Commercial Franchise						
U.S. Revenue	30.3	25.2	20%	80.1	70.9	13%
Nordic Revenue	9.7	9.9	-3%	35.8	33.7	6%
Partner Revenue	9.7	16.0	-40%	44.0	49.9	-12%
Revenue Adjustment *	-			-2.3		
Total Hexvix®/Cysview®	**49.6**	**51.1**	-3%	**157.5**	**154.4**	2%
Other Revenue	0.3	1.0		0.8	2.9	
Total Revenue	**49.9**	**52.1**	-4%	**158.3**	**157.3**	1%
Operating Expenses	-50.2	-44.9	12%	-160.6	-136.9	17%
EBITDA before restr.	**-3.7**	**2.6**		**-13.7**	**5.7**	
Development Portfolio						
Total Revenue	**-**	**8.7**		**0.3**	**8.7**	
Operating Expenses	-1.7	-2.9	-43%	-5.5	-10.2	-46%
EBITDA before Restructuring	**-1.7**	**5.7**		**-5.4**	**-1.6**	
Total Photocure						
EBITDA before Restructuring	**-5.4**	**8.3**		**-19.1**	**4.2**	

* Revenue Adjustment: Revenue Items for Previous Years Accounted for this Period

Commercial Franchise

- **U.S.:** Q3 Revenue increase of 20% reflecting rebound from Covid-19
  - Q3 unit sales 17% above last year
- **Nordic:** Q3 revenue decline mainly driven by sale from Covid-19 related safety stock replacing own sales
- **Partner:** Revenue decline in Q3 driven by less purchase and return of remaining inventory from Ipsen, impact in total NOK 8.9 million on revenue. Adjusting for this transition impact Q3 revenue increased 16%
  - Q3 unit sales increased 7% from last year
- **EBITDA:** Q3 at NOK -3.7 million. Adjusting for transition costs Q3 EBITDA at NOK 4.2 million, an improvement of 61% from Q3 2019

Development Portfolio

- Revenue Q3 2019 is sign-on fee from Asieris
- Operating expenses Q3 reduced YOY 43%

Consolidated Income Statement

Third Quarter 2020

Amounts in NOK million	Q3 '20	Q3 '19	Change	YTD '20	YTD '19	Change
Hexvix®/Cysview® Revenue	49.6	51.1	-3%	157.5	154.4	2%
Other Revenue	0.3	9.7		1.1	11.5	
Total Revenue	**49.9**	**60.8**	-18%	**158.6**	**166.0**	-4%
Gross Profit	**46.5**	**56.1**	**-17%**	**147.0**	**151.3**	**-3%**
Operating Expenses	-51.9	-47.8	8%	-166.1	-147.2	13%
EBITDA before Restructuring	**-5.4**	**8.3**		**-19.1**	**4.2**	
Depreciation & Amort.	-3.8	-4.0		-11.6	-12.4	
EBIT before Restructuring	**-9.2**	**4.3**		**-30.7**	**-8.3**	
Restructuring Expenses	-7.2	-		-10.4	-	
Net Financial Items	2.2	1.0		8.2	0.9	
Earnings before Tax	**-14.2**	**5.3**		**-32.8**	**-7.4**	
Tax Expenses	8.0	-5.9		0.2	-3.3	
Net earnings	**-6.2**	**-0.6**		**-32.6**	**-10.7**	

Revenue, Significant One-off Items

- Excluding one-off's Q3 YoY revenue increases 13%
  - Q3 2020: Transition items Ipsen NOK 8.9 million
  - Q3 2019: Sign-on fee paid by Asieris NOK 8.7 million

Operating Expenses

- Excluding transition costs Ipsen (NOK 1.5 million) YoY Q3 growth of 5%, mainly driven by foreign exchange

EBITDA

- Driven by transition costs Ipsen of NOK 7.9 million

Restructuring Expenses

- One-off costs related to setting up European organization

Net financial items

- Driven by foreign exchange

Cash Flow

Third quarter 2020

Amounts in NOK million	Q3 '20	Q3 '19	YTD '20	YTD '19
Operations Cash Flow	**-9.9**	**9.9**	**4.5**	**-9.8**
Earnings before Tax	-14.2	5.3	-32.8	-7.4
Working Capital	-4.2	1.8	10.2	-10.2
Other	8.5	2.9	27.1	7.8
Investments Cash Flow	**-166.4**	**-**	**-166.5**	**0.6**
Fixed & Intangible Assets	-0.1	-0.4	-1.4	-0.7
Return of Marketing Rights	-166.7	-	-166.7	-
Other	0.4	0.4	1.6	1.3
Financing Cash Flow	**-1.2**	**-0.7**	**358.5**	**-1.8**
Private Placements	-1.3	-	301.7	-
Loan	-	-	50.0	-
Other	-	-0.7	6.8	-1.8
Net Change in Cash	**-177.6**	**9.2**	**196.5**	**-10.9**
Ending Cash Balance	**321.8**	**95.9**	**321.8**	**95.9**

Cash Flow from Operations

- Q3 impacted by lower earnings than prior year as well as inventory return from Ipsen (working capital).
- YTD improvement driven by milestone payment of USD 1.5 million from Asieris

Cash Flow from Investments

- Q3 includes acquisition of marketing rights from Ipsen, EUR 15 million

Cash Flow from Financing

- YTD net proceeds from private placements of NOK 302 million as well as a loan provided of NOK 50 million

Cash Balance Quarter End

- Quarter end cash balance at 321 million after net cash outflow in Q3 of NOK 178 million

Balance Sheet

30 September 2020

Amounts in NOK million	2020 Sept. 30	2019 Sept. 30	2019 Dec. 31
Non-Current Assets	**226.7**	**73.1**	**70.5**
Investments	5.9	16.1	13.6
Marketing Rights	166.7	-	-
Tax Asset	38.5	49.1	38.3
Other	15.6	8.0	18.5
Current Assets	**381.7**	**143.5**	**186.9**
Inventory & Receivables	59.8	47.6	61.6
Cash & Equivalents	321.8	95.9	125.3
Total Assets	**608.4**	**216.6**	**257.4**
Shareholders Equity	491.8	166.4	208.6
Loan	50.0	-	-
Other Long-Term Liabilities	8.0	10.8	10.0
Current Liabilities	58.7	39.5	38.7
Total Equity & Liabilities	**608.4**	**216.6**	**257.4**

Non-Current Assets

- Net investments of NOK 5.9 million, driven by investments in Cysview phase 3 project. This project will be fully amortized in 2020
- Marketing rights NOK 166.7 million, acquired from Ipsen
- Deferred tax asset of NOK 38.5 million, reduced YoY mainly due to foreign exchange driven 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

Current Assets

- Inventory & receivables increased YoY, mainly driven by inventory including inventory return from Ipsen

Equity & Liabilities

- Shareholder's equity of NOK 491.8 million. Equity ratio of 81%
- Three-year term loan of NOK 50 million, floating interest rate
- Other long-term liabilities include impact from adoption of IFRS 16 (Leases)

Launching Hexvix® Operations in Europe on 1 October

Large Untapped Potential in the 150 Mill EUR European Market

Established Photocure Markets

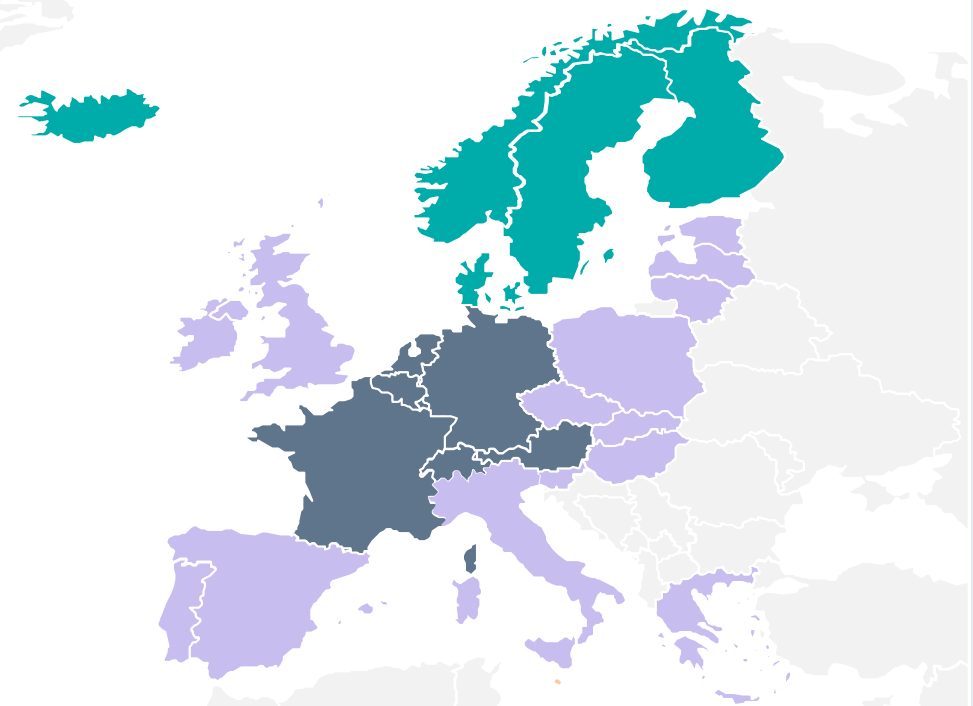
Nordics: 40% penetration

Commercialized countries by former partner

DACH region: 30-35% penetration
France: ~15% penetration

Untapped EU Markets

UK, Spain, Italy & other countries
~0% penetration



Europe	U.S.
Europe: 165,000 new cases and more than 50,000 deaths annually[1]	US: 82,500 new cases and more than 18,000 deaths annually[1]
EU5: 360,000 TURBTs	US: 315,000 TURBTs
Ave. Hexvix® price ~ EUR 420	Ave. Cysview® price ~ USD 1071
Germany: 30-35% current penetration, >3,500 units per sales FTE, growing	Penetration 5-10% Growth rate in excess of 35% Y-o-Y
Major markets like UK, Spain were not pursued, very limited resources in Italy, France	Increased commercial investment and focus delivering results

1.Globocan 2018 data on bladder cancer. Internal patient-based model supported by 3rd party sources
Potential = Total TURBTs in EU5 x Hexvix price

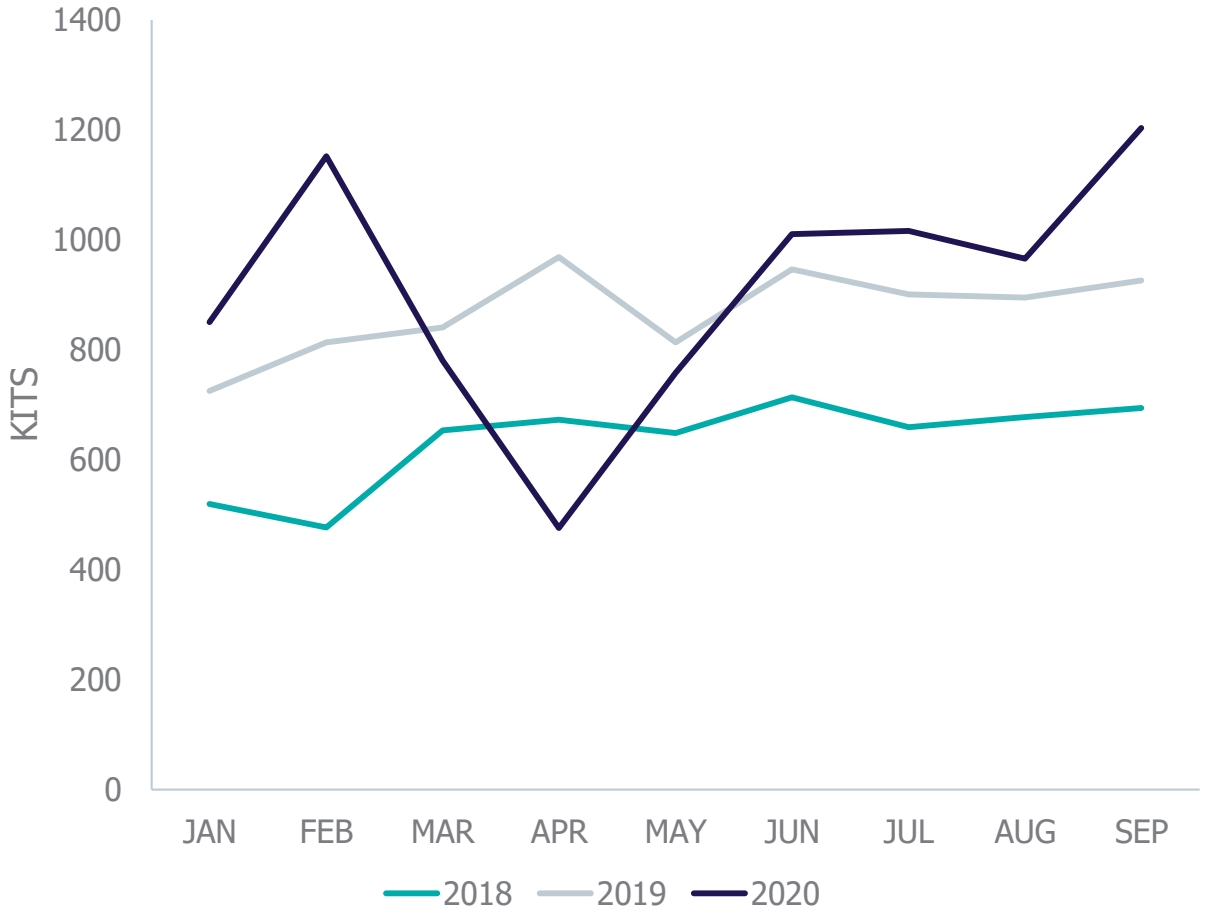
Launching Hexvix®
Operations in Europe

- Key commercial resources in place and direct promotion initiated on 1 October
- 100% of previously Ipsen DACH Hexvix sales force now employed by Photocure ensuring no disruption in service and support
- Distribution channels built across all of Europe
- Legal Entities established in Germany and France

U.S. Positioned for Growth

U.S. demonstrated strong signs of recovery in Q3

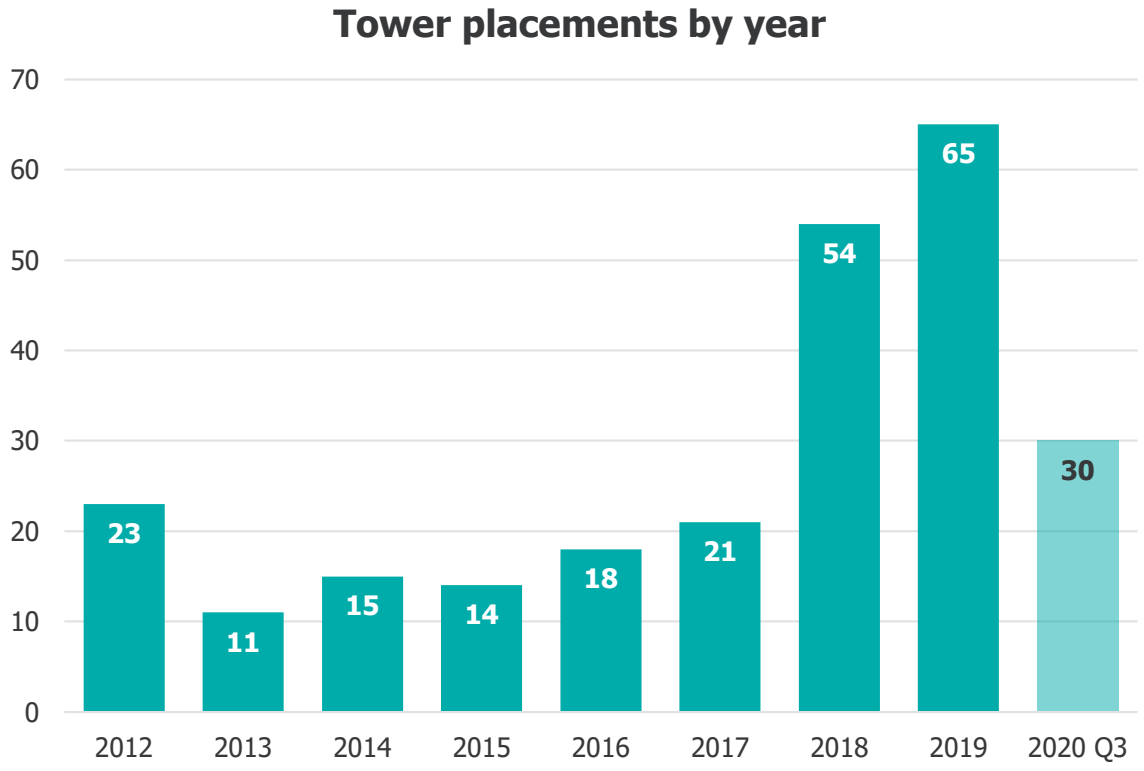
amidst Covid-19 resurges with 17% unit growth from Q3 2019



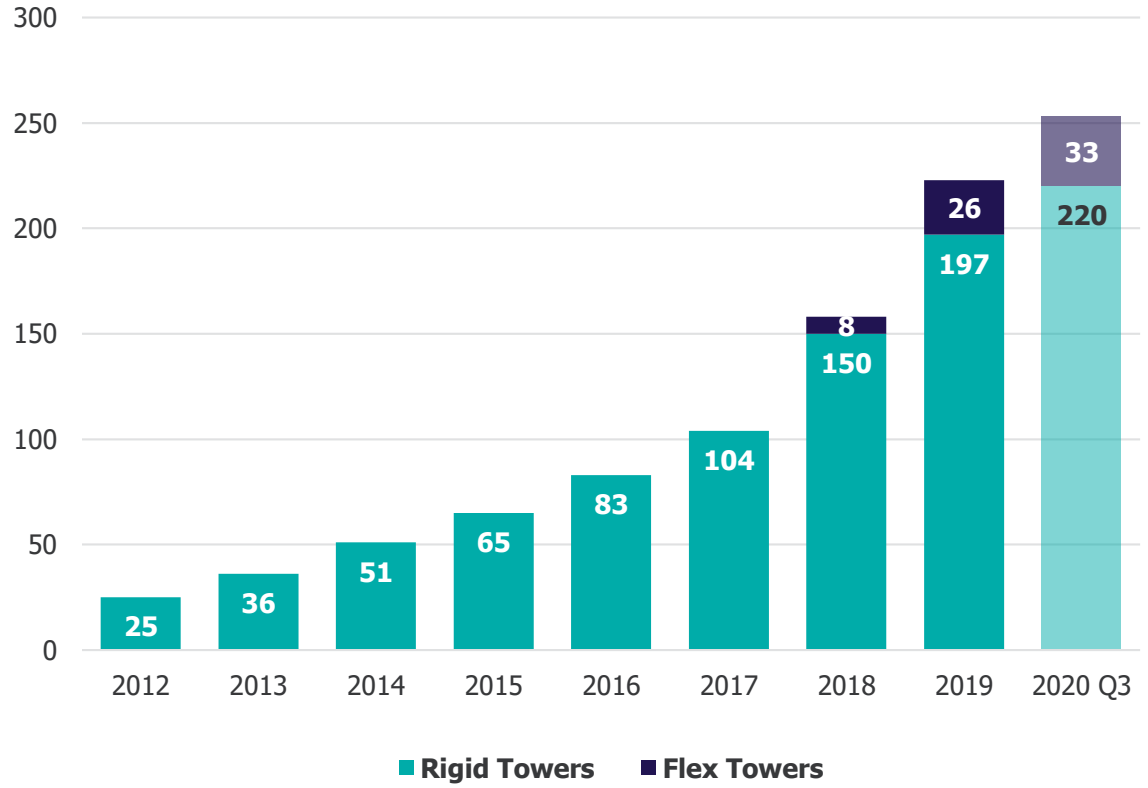
U.S.: Continued blue light cystoscope placements

despite challenges of pandemic

Annual New Installations



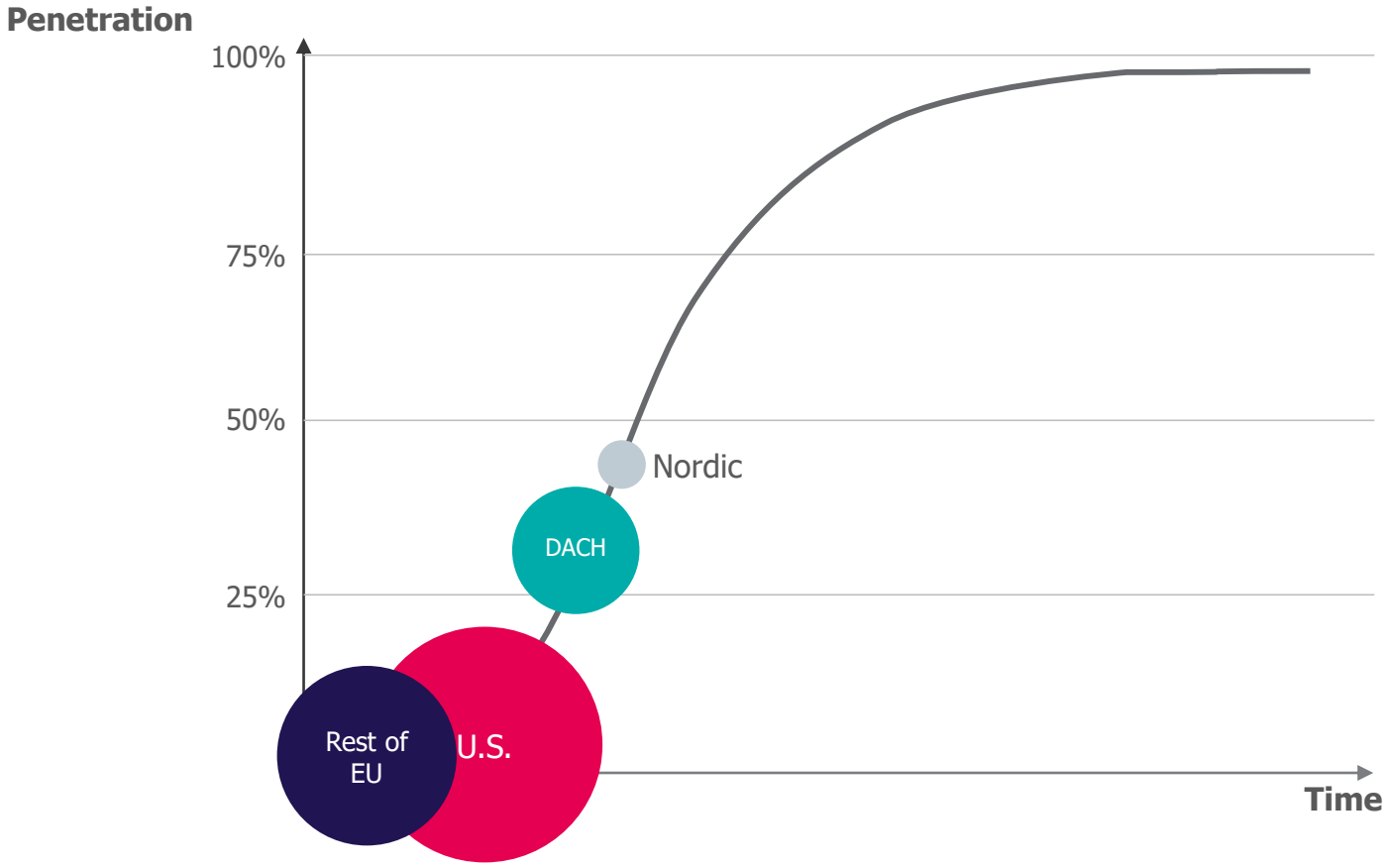
Cumulative install base continues strong trend



*2012 – 17 of the 23 installations were converted clinical sites upon Cysview approval

Hexvix®/Cysview® – key Market enablers in place: ready for growth and our Ambition to become the standard of Care

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

*AUA, EAU, SUO, AFU, NICE, DGU guidelines

Increasing media attention for the BLC® procedure and bladder cancer

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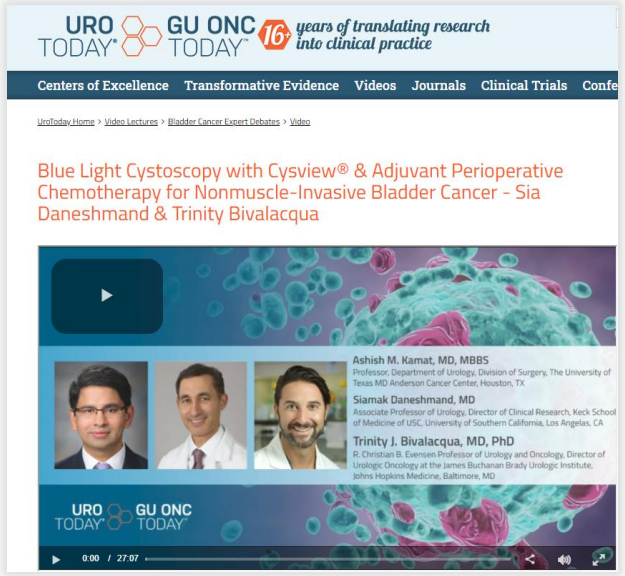
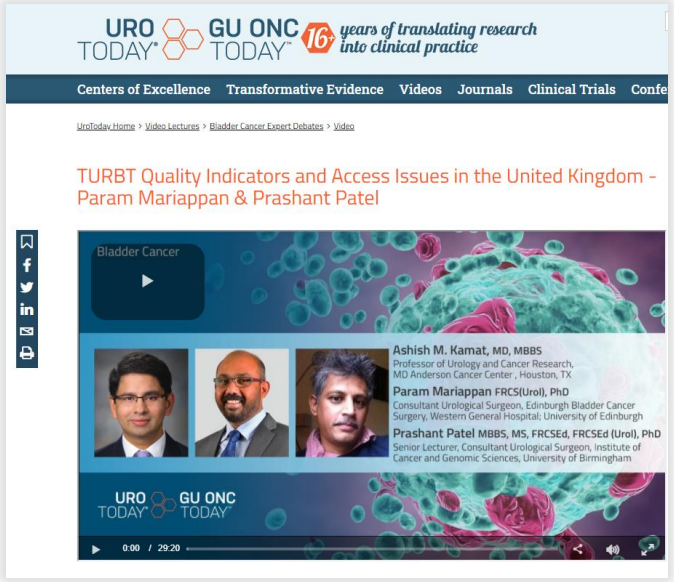
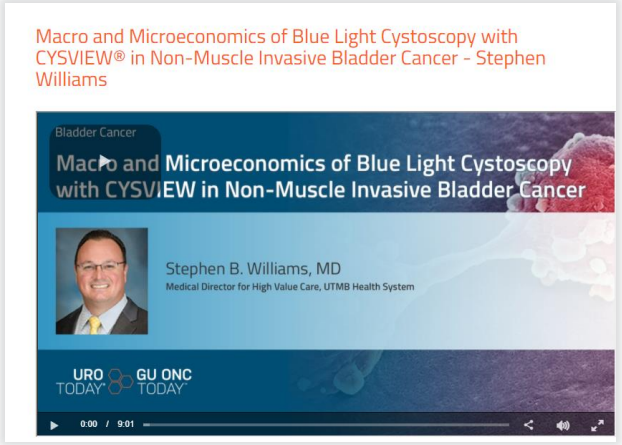


UroToday 11 and 24 June, 13 September 2020





AUA News article Sept 2020

Norwegian patient association magazine Sept 2020

Increasing media attention by Photocure taking over Hexvix in Europe markets

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Photocure leverer vekst

Optimismen rår.

LA FREM TALL: Daniel Schneider, CEO i Photocure. Mer ›

Helse

Photocure leverer Hexvix/Cysview-inntekter på 53,7 millioner kroner i andre kvartal, noe som tilsvarer tre prosent vekst sammenlignet med samme periode i fjor.

Blærekreftselskapet gikk på en skikkelig coronasmell i USA i starten av kvartalet, før markedet kom skikkelig tilbake mot slutten.

Photocure har fra fjerde kvartal inngått en salgs-, markedsførings- og distribusjonsavtale for Hexvix med Ipsen Pharma SAS, og ser betydelig vekst i Europa. Avtalen ventes å få effekt for EBITDA (driftsresultat før av- og nedskrivninger) fra helåret 2021 og fremover.

Finansavisen 18 August 2020

DAGENS Medisin Pharma

Apotek og legemidler

Photocure kjøper tilbake Europa-rettighetene til Hexvix: – Vi ser store muligheter

– Vi mener vi nå er mye bedre rustet for å øke salget av Hexvix innenfor Europa, blant annet basert på de erfaringene vi nå har fått fra USA og Norden, sier finansdirektør Erik Dahl i Photocure.

Dagens Medisin 5 October 2020

Photocure overtar salget av Hexvix i Europa - forventer en tredobling av inntektene i 2021

Legemidler og biotek

Photocure har inngått en avtale med legemiddelselskapet Ipsen Pharma om å ta tilbake de kommersielle rettighetene for salg og markedsføring av Hexvix i Europa. Dette et ledd i vår strategi om å bli en global leder innen blærekreft, sier Dan Schneider.

Foto: Getty Images

Hans Andenæs | 06.10.2020

Photocure har inngått en avtale med legemiddelselskapet Ipsen Pharma om å ta tilbake de kommersielle rettighetene for salg og markedsføring av Hexvix i Europa. - Photocure ser betydelige vekstmuligheter i Europa, sier administrerende direktør Dan Schneider.

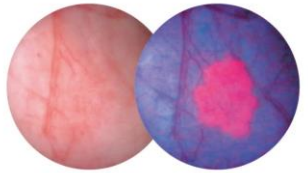
De kommersielle rettighetene overføres til Photocure fra og med 1. oktober 2020.

- Når vi nå tar full kontroll over Hexvix i Europa, er dette et ledd i vår strategi om å bli en global leder innen blærekreft og kontrollen gir oss et solid fundament for for videre vekst, sier Schneider. Photocure tar over salget i Europa allerede fra fjerde kvartal 2020.

Tredobling i 2021

I 2011 inngikk Photocure en global kommersialiseringsavtale med Ipsen om salg, markedsføring og distribusjon av Hexvix utenfor Norden, og USA. Ipsen har fungert som strategisk partner og har bygget en solid posisjon for merkevaren i utvalgte, viktige europeiske markeder.

Hexvix injiseres i blæren gjennom et kateter. Deretter gjennomføres en cystoskopi med blått lys, fremfor det tradisjonelle hvite lyset. Dersom kreft er til stede vil den glade radt under det blå lyset. Slik oppdages kreft som ikke er synlig ved bruk av tradisjonell cystoskopi med hvitt lys.



Ved bruk av Hexvix sammen med et blått lys på cystoskopet, vil forandringer i vevet vises i form av endret fargestruktur. Svulsten(e) vil da lyse rødt mot en blå bakgrunn, noe som gjør at urologene oppdager kreft som ikke er synlige med standardmetoden hvitt lys som vises i bildet til venstre.

I 2019 oppnådde Ipsen et Hexvix-salg på 203 millioner kroner i det europeiske markedet, med unntak av Norden der Photocure gjennom alle år har hatt fullt ansvar for salg og markedsføring. Photocures royalty av dette var 61 millioner kroner. Nå tror Photocure-sjefen at det allerede i 2021 vil være mulig å tredoble dette beløpet når Photocure tar over salg og markedsføring. Etter 2021 forventer Schneider en årlig omsetningsvekst på om lag 20-30% i de tidligere Ipsen-markedene.

Må investere

Men for å få tilgang til denne inntektsstrømmen må Photocure gjøre omfattende investeringer. Selskapet varsler at det vil påløpe 30-35 millioner kroner i integrerings- og oppstartskostnader i 2020, og om lag 90 millioner kroner i økte salg- og andre kostnader (SG & A) i Europa fra 2021.

De viktigste vekstområdene for Photocure er de amerikanske og europeiske markedene der det er store uutnyttede markedsmuligheter. Selskapet ser betydelige vekstmuligheter i Europa og andre land som for øyeblikket ikke er kommersialisert av Ipsen.

- Når vi nå tar full kontroll over Hexvix i Europa, er dette et ledd i vår strategi om å bli en global leder innen blærekreft og kontrollen gir oss et solid fundament for for videre vekst, sier Dan Schneider.

Hexvix og Kreft i urinblæren

Photocures flaggskip-medikament heter Hexvix/Cysview og retter seg mot blærekreft.

Vis mer

HealthTalk Norway 6 October 2020

Photocure har ansatt Susanne Strauss som leder for satsingen i Europa

Hennes første arbeidsdag er i dag, 1. juli.

EUROPA-SATSING: Her fra Bærum sykehus, der en pasient får operert bort kreft i urinblære... Mer ›

Helse

Henning Christensen

16:12 - 1. juli

Photocure har ansatt Susanne Strauss som Europa-sjef, opplyses det i en melding.

Hun går inn i stillingen som konserndirektør og leder for Europa med virkning fra i dag, 1. juli, og vil rapportere direkte til Photocure-sjef Dan Schneider.

Finansavisen 1 July 2020

TIL PHOTO... Mer ›

Photocure lanserer egen europeisk organisasjon til høsten, som Strauss skal lede. Inn i denne organisasjonen vil også den nordiske driften, som i dag ledes av Kristin Nyberg, bli integrert.

Strauss har mer enn 20 års ledererfaring innen medisinsk utstyr, biovitenskap og farmasi, fra Europa, Asia og USA.

Hennes seneste jobb var som leder for britiske BTGs virksomhet i Asia og Stillehavsområdet. BTG ble i fjor overtatt av amerikanske Boston Scientific. Tidligere har hun hatt lederroller i selskaper som Convatec, Janssen-Cilag og Baxter, opplyses det.

Photocure viser til at selskapet i år tar tilbake kontrollen over salgs-, markeds- og distribusjonsrettighetene for Hexvix i Europa og andre markeder fra Ipsen Pharma, og at det i den forbindelse etableres egen kommersiell drift på det europeiske markedet.

Strauss skal blant annet etablere et europeisk hovedkontor for Photocure og ansette et kommersielt team samt utvikle nye vekststrategier i viktige europeiske markeder.

Summary and outlook

Guidance: approximately 1bn revenue in 2023

Current-year guidance:

In Q3 the rebound continued

Potential increased pressure on revenue in Q4 due to COVID-19 impact:

- Hospitals are better prepared for a second wave of the pandemic
- Procedures may be postponed
- Restricted access to the OR
- Capital equipment budgets are being temporarily reprioritized, impacting installed base growth in the near term

Our Mission: Delivering transformative solutions to improve the lives of bladder cancer patients

PHOTOCURE® THE BLADDER CANCER COMPANY

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

Ambition of worldwide revenues in range of **NOK 1 Billion** in 2023
and approximate **40% EBITDA** margin in 2023

Leading change in bladder cancer

Q&A