

# Photocure ASA 3<sup>rd</sup> Quarter 2024 Results

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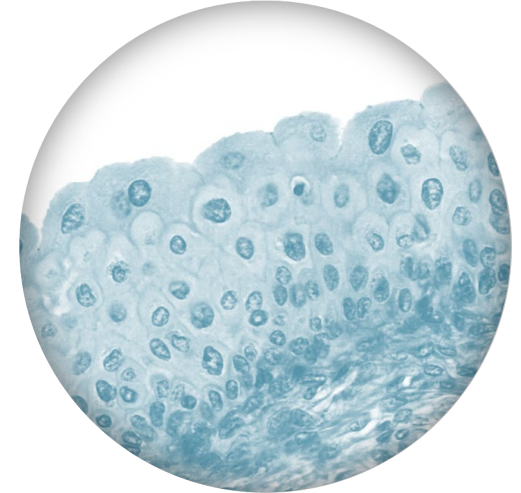
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# Strategic Priorities & Initiatives



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## Continue to grow Hexvix<sup>®</sup>/Cysview<sup>®</sup> sales and increase Company profitability

- Deliver on our guidance for product revenue, EBITDA and new tower placements
- Collaborate with ForTec on Mobile BLC rollout
- Drive additional account reactivations in U.S. and image quality upgrades in Europe
- Increase penetration in Priority Growth Markets in Europe
- Leverage Olympus' launch of new HD BLC system in Nordics/EU

## Develop BLC's role as a definitive diagnostic in bladder cancer care / Improve access

- Position BLC as the primary diagnostic tool to facilitate earlier use of new NMIBC therapeutics
- Support reclassification of BLC equipment in the U.S.: Citizen's petition/Partnerships
- Collaborate with BLC equipment manufacturers who plan to enter the U.S.
- Reintroduce Flex BLC with state-of-the-art system via partnership with Richard Wolf

## Expand product portfolio / Diversify global product offering in bladder cancer / uro-oncology

- Continue to assess opportunities within NMIBC & other uro-oncology indications: Biomarkers, AI, new technologies
- Leverage existing global commercial infrastructure in broader uro-oncology segment

# 3<sup>rd</sup> Quarter 2024 Highlights:

*Continued growth and execution on key initiatives*



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## Product Revenue +12%

Q3 unit sales +8%

### Expanding U.S. Saphira™ footprint

- 6 new account towers installed
- 6 upgrades from existing accounts

### Executing on plan in Europe

- Priority Growth Markets grew 12% in Q3
- Largest region, DACH countries maintaining good growth

### Ongoing challenges:

- Phase down of flex BLC utilization
- Single manufacturer in the U.S.
- Delay of Olympus' upgraded BL to Q4 2024

## EBITDA NOK 5.0 million

NOK 6.3 million ex-BD expense

**Photocure continues to contain expense growth** and invest behind Hexvix/Cysview

**Biz Dev expense** NOK 1.3 million

### Strong Balance Sheet

NOK 291 million in cash and equivalents, up from NOK 260 million at year-end 2023.  
No term debt

## Recent news and key milestone events

### Richard Wolf Flex Agreement:

Partnership to develop & commercialize state-of-the-art HD flexible BLC system globally (July)

### ForTec Mobile BLC Strategy:

National rollout in U.S. showing good momentum

### Named Patient Program (NPP):

Enables bladder cancer patients in South Africa access to BLC with Hexvix (Sept.)

**Asieris Progress:** Early approval of Hexvix in China (November). Cevira® Phase III data presentations at 2024 PDT & PD Conference & CSCO Annual Meeting in Q3.

# Segment Trends

North America and Europe markets



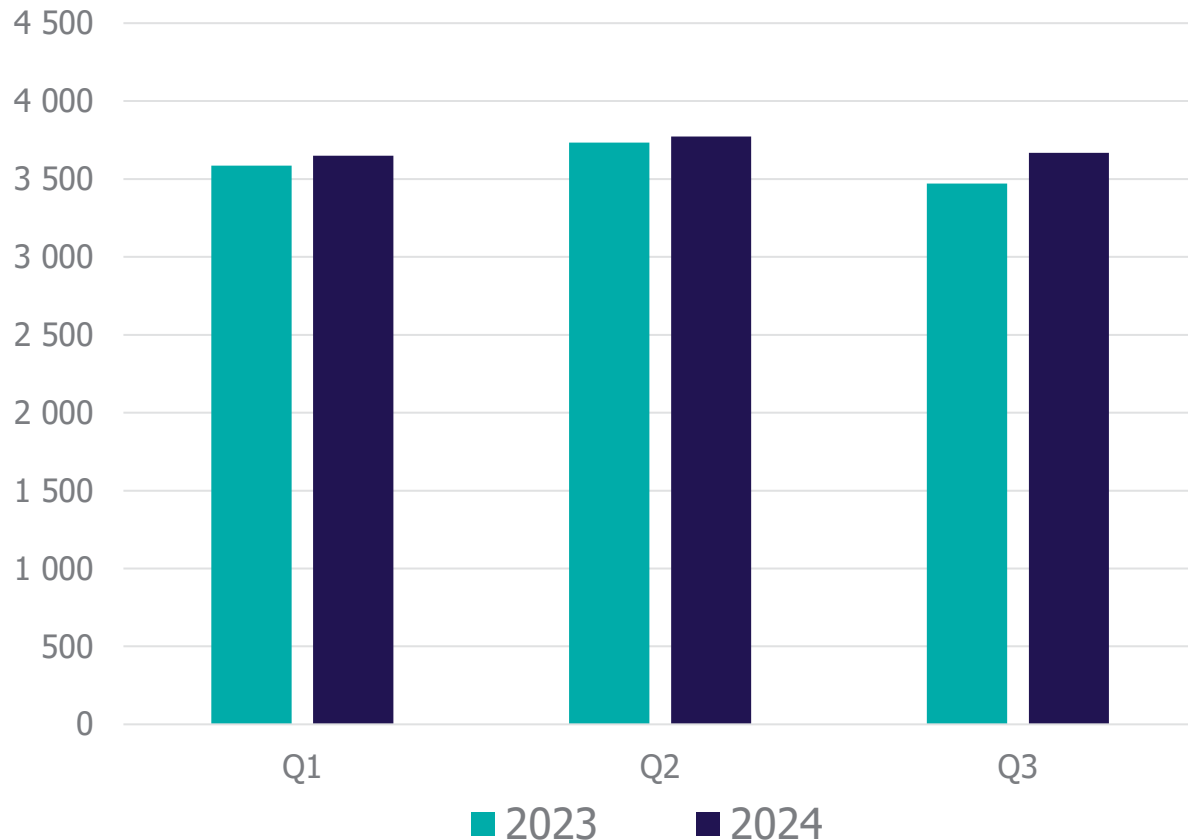
# Solid Unit Sales Performance in Both Regions in Q3



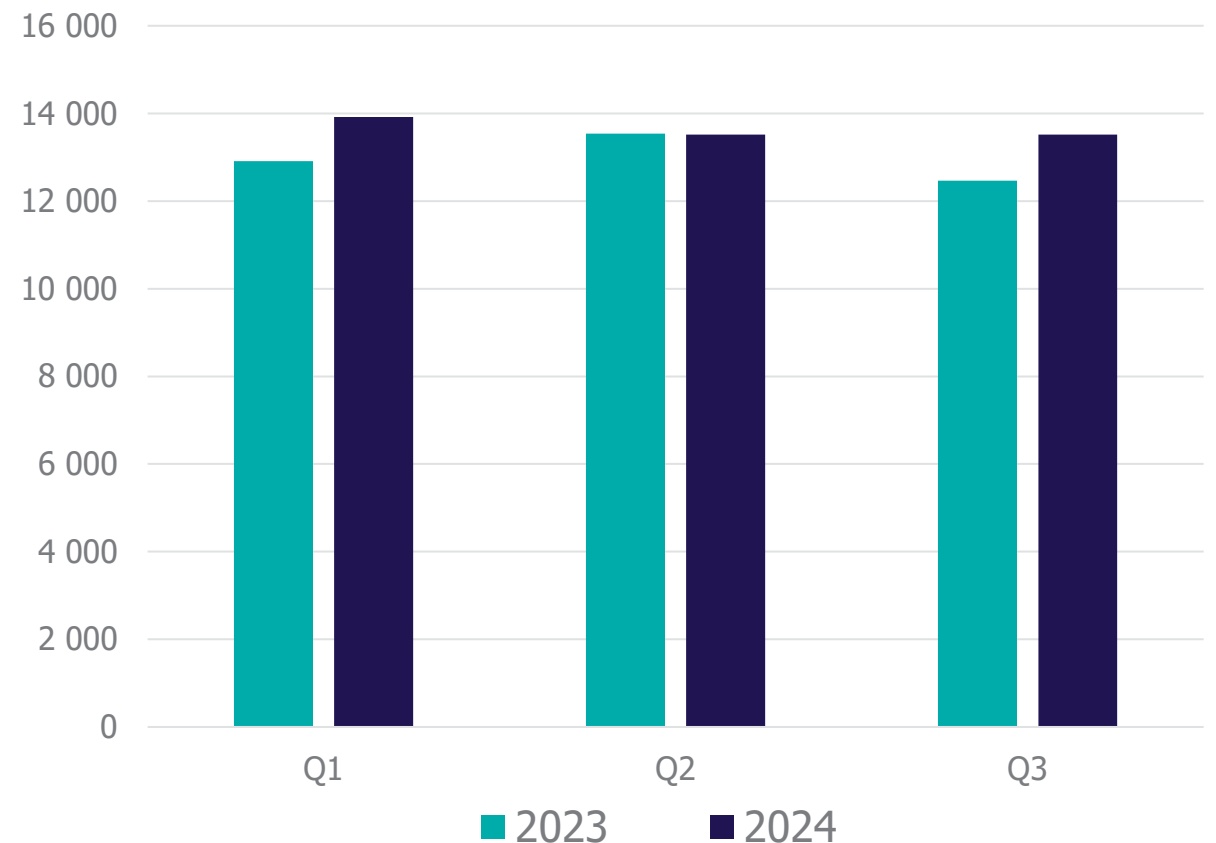
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*Quarterly Hexvix/Cysview Unit Sales by Region (Last 2 Years)*

## North America



## Europe



# Q3 2024 Trends in North America



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- **Q3 2024 revenues increased 12%, in-market unit sales rose 6%.** Higher average price benefited revenues, Cysview growth in rigid segment outpaces flexible BLC phase down again (**10% sales growth in rigid segment through Q3 2024**)
- **Installed base of rigid BLC equipment continues to increase;** 12 Saphira™ installs (6 new towers, 6 upgrades). Karl Storz BLC tower promotional program to remain in effect through year-end 2024.
- **ForTec mobile BLC national rollout gaining traction in U.S.:** 18 towers deployed as of August 2024; 30 accounts have used the service as of Sept. 30.
- **Access to BLC and reclassification in U.S. remains a focus**  
Comments unanimously support the Citizen's Petition\*, including those from KOLs, BCAN (U.S. Patient Advocacy), health systems, Pacific Edge (biomarkers), Richard Wolf, Stryker and Olympus

AUA News  
Sponsored by Photocure, Inc.

**ADVANCING NMIBC DIAGNOSTICS WITH ENHANCEMENTS IN BLUE LIGHT CYSTOSCOPY**

With an enhanced ability to visualize NMIBC lesions using Blue Light Cystoscopy (BLC®), Dr. Shreyas Joshi M.D., M.P.H., recounts a recent case of a younger patient with recurrent non-muscle invasive bladder cancer (NMIBC) whose course of treatment was greatly influenced by the enhanced tumor detection provided by BLC.

[Read More >](#)

LEARN MORE DO YOU WANT BETTER VISIBILITY during TURBT procedures?

Photocure advertorial with KOL interviews in AUA News starting July 2024

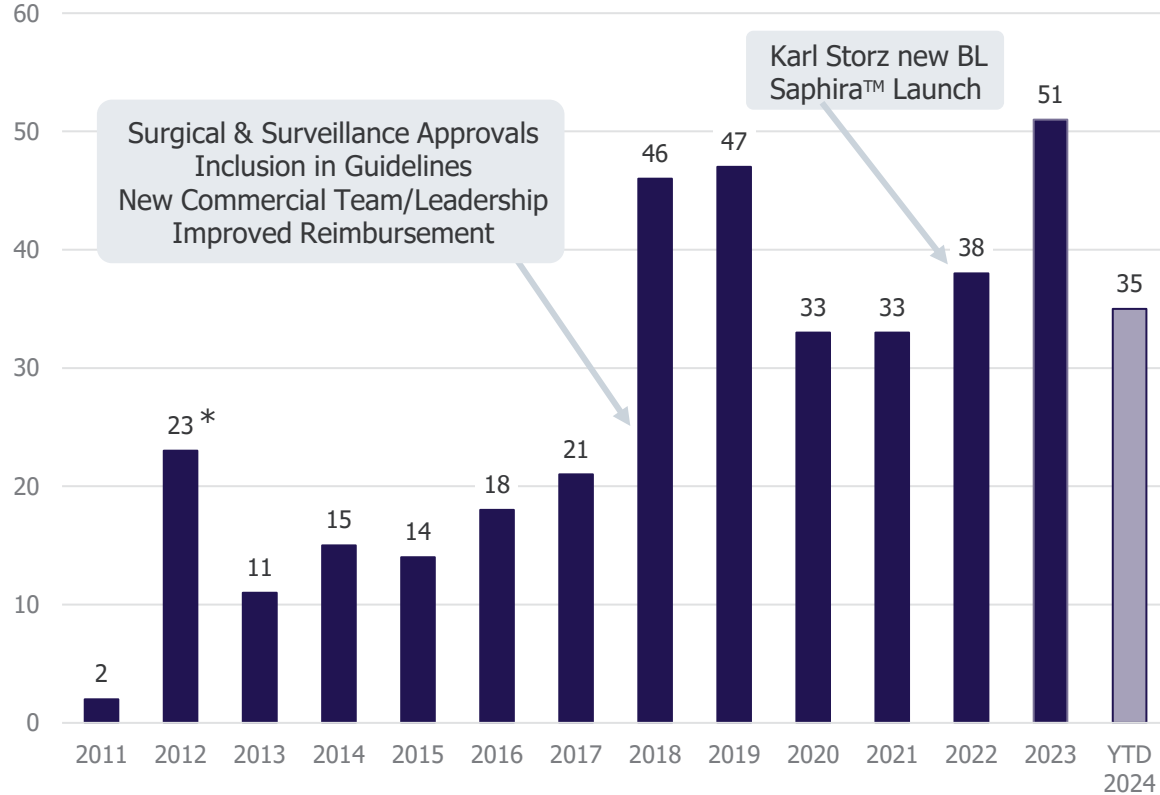
# Saphira™ now 48% of rigid BLC installed base in U.S.



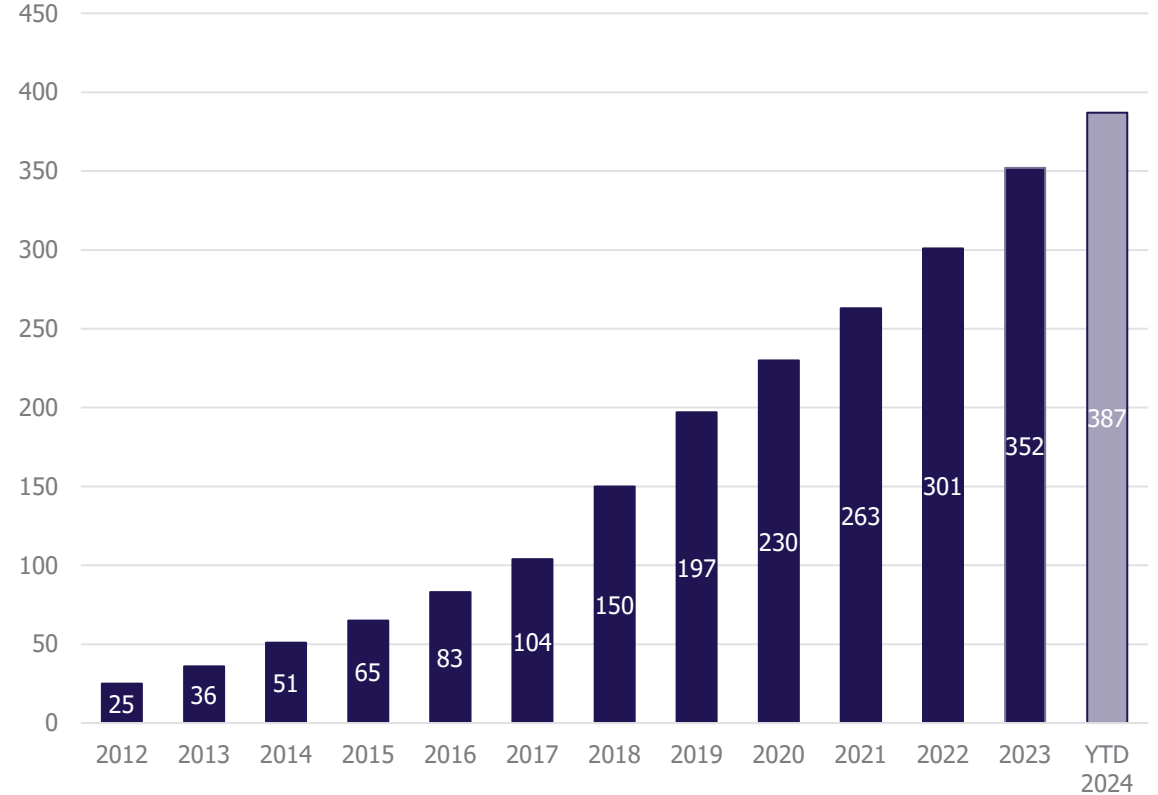
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12 tower installations in Q3 2024 (6 new accounts, 6 upgrades); 49 Saphira systems placed YTD

## Annual New BLC Rigid Tower Installations



## Cumulative Installed Rigid Tower Base in U.S.



### New & Mobile Rigid Tower Installations

Q4 2023: 10 installations  
 Q1 2024: 12 installations (6 New, 6 Mobile)  
 Q2 2024: 17 installations (5 New, 12 Mobile)  
 Q3 2024: 6 installations

### 186 Saphira™ towers installed since Q3 2022 launch;

98 New, 70 Upgrades and  
 18 Mobile towers

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



# Q3 2024 Trends in Europe

- **Q3 revenues increased 12% year-over-year, in-market unit sales grew 9%.** Revenue increase was mainly due to growth in Germany and Priority Growth Markets
- **Executing on plan to increase Priority Growth Market penetration**  
UK continues to have strong double-digit growth, France achieved 9% growth, Italy trending well
- **Strong BLC presence at national congresses** in Italy and Germany in Q3. Continuing support to KOLs and medical education
- **Key initiatives to accelerate unit sales growth:**
  - 1,400 TURBT-performing centers, approximately 50% have BL equipment
  - Actively targeting 590 key hospitals/clinics; approximately 2/3 still underpenetrated
    - 44 image quality upgrades in Q3; 220 since 2023 to date in our target accounts
    - Added 29 new accounts in 2023 and 2024 YTD
    - Preparing for co-launch of Olympus upgraded blue light system - anticipated Q4 2024



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Photocure after work with Olympus equipment exhibit at DGU, Leipzig, Germany, September 2024

# Growth initiatives



# Growth initiatives



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## Accelerating BLC through Mobile Capability in the U.S.: ForTec

- Nationwide sales collaboration doubling BLC's footprint with new ForTec customers
- On Demand capability: On-demand utilization of BLC via operating budgets
- 18 Towers deployed and building demand
- Teams leveraging both partners' customer infrastructure

## Flexible BLC equipment to unlock the global surveillance market: Richard Wolf

- Strategic agreement to develop and commercialize a next generation 4K LED HD reusable flexible blue light cystoscope
- IP and Regulatory responsibilities remain with RW
- Photocure and Richard Wolf will invest in development and co-promote globally
- Estimated Total Addressable Market: 1.3B USD

## Leverage opportunities stemming from the rapidly evolving NMIBC treatment landscape

- 3 new FDA approved products / Multiple drug companies conducting 20+ clinical trials: multiple MOAs/ drug targets
- Tumor resection, biopsies and pathology will still be required for definitive staging and grading
- BLC to play an important role in supporting new "bladder sparing" therapies: patient selection, staging, marker lesion identification



# Value-generating Asieris Programs:

## Hexvix: Commercial partnership in China

### Past Progress

**Phase III Trial  
Endpoint  
successfully met.**

**1<sup>st</sup> Data presented at  
SIU Congress in Oct  
2023**

**Strong Results  
(p<0.0001)**

**First RCT Trial  
Conducted with High  
Def. BLC equipment**

### Recent News & Expectations

**Chinese Authorities'  
(NMPA) Review of  
NDA ongoing since  
Nov 2023  
(Typically 18 Months!)**

**Market Authorization  
Granted Early in China  
(November 5, 2024)**

**Regulatory Approval of  
BL Equipment**

**Commercialization**

### Potential for Photocure

**Photocure/Asieris Joint  
Steering Committee  
Development of Hexvix  
Brand in China/Taiwan  
Milestone, Royalty, and  
Manufacturing Revenue  
on Sales**

## Cevira: Out-licensed worldwide rights to Asieris for development/commercialization

### Past Progress

**1st Non-Invasive  
Candidate for  
Cervical HSIL;**

**Phase III Endpoint  
met. Results China &  
Europe**

**Phase III Trial  
Results presented at  
the EUROGIN 2024  
HPV Congress in  
March 2024**

### Recent News & Expectations

**NDA accepted in  
China May 2024,  
review by NMPA  
ongoing**

**EU Pre-MAA submission  
and US FDA discussions  
anticipated in Q4,**

**Commercialization in  
China / Potential MAs  
in other regions**

### Potential for Photocure

**Regulatory Milestones;  
Royalties and Sales  
Milestones**

# Q3 Financials



# Consolidated Income Statement

## Third Quarter 2024



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<i>Amounts in NOK million</i>	Q3 '24	Q3'23	Change	YTD '24	YTD '23	Change
Hexvix/Cysview Revenue	120.1	107.3	12%	359.3	329.1	9%
Other Revenue	0.1	0.3		24.4	29.0	
<b>Total Revenue</b>	<b>120.2</b>	<b>107.5</b>	12%	<b>383.7</b>	<b>358.1</b>	7%
<b>Gross Profit</b>	<b>112.4</b>	<b>100.7</b>	12%	<b>360.5</b>	<b>337.9</b>	7%
Operating Expenses excl BD	-106.1	-96.7	10%	-316.4	-302.0	5%
Business Development Expenses	-1.2	-0.6		-3.3	-10.3	
<b>EBITDA – excluding BD</b>	<b>6.3</b>	<b>3.9</b>		<b>44.1</b>	<b>35.8</b>	
<b>EBITDA – including BD</b>	<b>5.0</b>	<b>3.3</b>		<b>40.7</b>	<b>25.6</b>	
Depreciation & Amortization	-7.2	-7.2		-21.5	-20.2	
<b>EBIT</b>	<b>-2.2</b>	<b>-3.9</b>		<b>19.2</b>	<b>5.3</b>	
Net Financial Items	-2.8	-4.8		-12.0	-12.1	
<b>Earnings before Tax</b>	<b>-4.9</b>	<b>-8.7</b>		<b>7.2</b>	<b>-6.8</b>	
Tax Expenses	1.5	3.9		-6.2	-5.4	
<b>Net earnings</b>	<b>-3.5</b>	<b>-4.8</b>		<b>1.0</b>	<b>-12.2</b>	

### Revenue

- Hexvix/Cysview product revenue increased 12% YoY, driven by unit sales increase of 6% in U.S. and 9% in Europe. Higher average pricing in the U.S. further contributed to the revenue growth
  - Consolidated volume impacted by phase down of Cysview usage in the flexible BLC setting in U.S.
- Other revenue YTD includes Asieris milestone payments in both years

### Operating Expenses

- Q3 total operating expenses excluding BD increased 10% YoY mainly driven by the timing of expense capitalization in Q3 2023 and timing of project expenses in 2024.
- Operating expenses within business development projects relate mainly to life cycle management for Hexvix/Cysview

### EBITDA

- Q3 EBITDA including BD expenses was NOK 5.0 million

### Net Financial Items

- Include Ipsen earn-out payments

# Segment Performance Third Quarter 2024



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## North America Segment

<i>Amounts in NOK million</i>	Q3 '24	Q3 '23	Change	YTD '24	YTD '23	Change
<b>Total revenues</b>	<b>49.0</b>	<b>43.6</b>	12%	<b>146.9</b>	<b>132.0</b>	11%
Gross profit	47.3	42.2	12%	142.3	127.7	11%
<i>% of revenue</i>	<i>97%</i>	<i>97%</i>		<i>97%</i>	<i>97%</i>	
Direct costs	-42.7	-34.2	25%	-129.2	-122.6	5%
<b>Contribution <sup>(1)</sup></b>	<b>4.6</b>	<b>8.0</b>		<b>13.2</b>	<b>5.2</b>	
<b>EBITDA</b>	<b>-6.9</b>	<b>-2.2</b>		<b>-17.1</b>	<b>-24.2</b>	
<i>% of revenue</i>	<i>-14%</i>	<i>-5%</i>		<i>-12%</i>	<i>-18%</i>	

- Q3 revenue growth of 12% was driven by unit sales growth in the rigid BLC setting and higher average price, partially offset by the phase down of Cysview usage in the flexible BLC setting
  - In-market unit sales increased 6%, average price increase 5%
- Q3 direct costs increased YoY mainly due to capitalization of registry expenses in Q3 2023 and the timing of project expenses in 2024
- YTD contribution increased by NOK 8.0 million YoY

## Europe Segment

<i>Amounts in NOK million</i>	Q3 '24	Q3 '23	Change	YTD '24	YTD '23	Change
<b>Total revenues</b>	<b>71.1</b>	<b>63.4</b>	12%	<b>212.4</b>	<b>196.7</b>	6%
Gross profit	65.0	58.2	12%	194.4	181.9	5%
<i>% of revenue</i>	<i>91%</i>	<i>92%</i>		<i>92%</i>	<i>92%</i>	
Direct costs	-30.0	-29.1	3%	-87.1	85.7	2%
<b>Contribution <sup>(1)</sup></b>	<b>35.1</b>	<b>29.1</b>		<b>107.3</b>	<b>96.3</b>	
<b>EBITDA</b>	<b>15.3</b>	<b>10.4</b>		<b>53.1</b>	<b>43.5</b>	
<i>% of revenue</i>	<i>21%</i>	<i>16%</i>		<i>25%</i>	<i>22%</i>	

- Q3 revenue increased 12% YoY
  - In-market unit sales increased 9%, impact of FX impact was approximately 3%
- Q3 direct costs increased 3%YoY, mainly driven by FX
- Q3 Contribution improved YoY by NOK 6.0 million and YTD by NOK 11.0 million, driven by revenue growth and cost containment

# Cash Flow & Balance Sheet Third Quarter 2024



<i>Amounts in NOK million</i>	Q3 '24	Q3 '23	YTD '24	YTD '23
<b>Operations Cash Flow</b>	<b>34.5</b>	<b>8.7</b>	<b>61.3</b>	<b>28.7</b>
Earnings before tax	-4.9	-8.7	7.2	-6.8
Depreciation & amortization	7.2	7.2	21.5	20.2
Working capital	23.9	1.8	5.3	-10.0
Other	8.3	8.4	27.3	25.2
<b>Investments Cash Flow</b>	<b>2.4</b>	<b>-2.5</b>	<b>3.1</b>	<b>-1.8</b>
<b>Financing Cash Flow</b>	<b>-12.9</b>	<b>-10.0</b>	<b>-32.8</b>	<b>-39.9</b>
<b>Net Change in Cash</b>	<b>24.1</b>	<b>-3.9</b>	<b>31.5</b>	<b>-13.0</b>

<i>Amounts in NOK million</i>	30.09.24	31.12.23
Non-current assets	322.1	339.5
Inventory & receivables	107.3	112.9
Cash & short-term deposits	291.1	259.5
Equity	499.7	482.8
Long-term liabilities	143.5	151.6
Current liabilities	77.3	77.5
<b>Total balance</b>	<b>720.5</b>	<b>712.0</b>

## Cash Flow

- Q3 cash flow from operations was NOK 34.5 million, driven by EBITDA adjusted for non-cash expenses and working capital
  - Working capital decreased mainly due to lower receivables and non-cash items including accruals and cost of the Company's employee option program
- Q3 cash flow from investments includes interest received, partially offset by investments in tangible and intangible assets
- Q3 cash flow from financing of NOK -12.9 million includes earnout payments to Ipsen of NOK 9.8 million
  - Term loan was fully repaid in Q2 2023
- Net cash flow in Q3 was NOK 24.1 million, cash balance end of Q3 was NOK 291.1 million

## Financial position

- Non-current assets include intangibles and goodwill from Ipsen transaction totaling NOK 244.0 million
- Long-term liabilities includes deferred Ipsen earnout totaling NOK 120.3 million
- Equity at September 30, 2024 was NOK 499.7 million, 69% of total assets



# Summary



# Summary of Q3 2024 results

- 12% Product rev. growth, unit sales up 8% YoY; executing on key initiatives to increase sales growth
- EBITDA of NOK 5.0M (NOK 6.3M Ex-BD); Commercial businesses contribution-positive in Q3 & prior 4 quarters
- 12 Saphira™ towers installed in U.S. (6 new, 6 upgrades); ForTec national mobile rollout gaining traction
- Installed base of 186 Saphira™ towers since launch; these now represent 48% of rigid towers in U.S.
- Flex phase-down remains a challenge, but growth of rigid (TURBT) towers & kit sales outweighed Flex pressure
- Priority Growth Markets in Europe responding well to turn-around efforts, 12% growth in these markets in Q3
- Strong momentum for NMIBC & BLC ; KOL support/equipment upgrades/new NMIBC therapies coming to market
- Cash balance strong at NOK 291 million, up from NOK 260 million at year-end 2023; no term debt

# Anticipated Milestones & Corporate Objectives



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- 2024 financial guidance reiterated: 6-9% product revenue growth (constant currency), positive EBITDA ex BD spend, and U.S. Saphira™ tower placements in the range to 55-70 (new + upgrades)
- Continue increasing Hexvix/Cysview kit throughput and tower upgrades & installations: collaborate with ForTec on mobile tower national rollout in U.S. / focus on growth markets & Olympus equipment launch in Europe
- Proactively support the Citizen's Petition for the U.S. FDA to reclassify BLC equipment from Class 3 to Class 2, potentially creating an expedited pathway for additional BLC manufacturers to enter the U.S. market
- Present/publish additional data from real world evidence patient registries and other studies supporting the use of BLC® with Hexvix/Cysview; leverage Photocure's U.S. registry with NMIBC therapeutic companies
- Advance partnership with Richard Wolf to develop and commercialize a next-generation Flexible BLC system for the global markets as soon as possible
- Asieris progress: Hexvix approved several months early in China; NDA for Cevira undergoing regulatory review. Pre-MAA submission for Cevira in EU and FDA discussions on U.S. filing requirements planned for Q4

# Leading change in bladder cancer

## Q&A