

Photocure ASA

3rd Quarter 2023 Results

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3rd Quarter 2023 Highlights:



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Growth limited as flexible BLC phase down continues; positive milestones achieved in Q3

Product Revenue +11%

Unit sales -1% year-over-year

21 Saphira™ Towers Installed Q3:

- 15 new accounts opened in U.S.
- 6 upgrades of existing accounts
- 64 Saphira™ towers placed YTD U.S.
- 100+ quotes outstanding

Executing on Plan in Europe

- 130 image quality upgrades YTD
- 15 new accounts opened YTD
- 27 Saphira™ POs pending

Ongoing challenges:

- Phase down of flex BLC utilization
- Staffing shortages slowly resolving

EBITDA NOK 3.3 million

NOK 3.9M ex-BD expense

OPEX mostly level excluding FX & BD last 8 quarters; Continued investment behind Hexvix/Cysview

Biz Dev expense NOK 0.6 million

Strong Balance Sheet

NOK 255 million in cash and equivalents; term debt fully paid off in Q2 2023

Key news and milestone events

Asieris' Cevira® Phase III trial met primary endpoint: Plans to present data at a medical conference

Hexvix Phase III trial met primary endpoint: high statistically significant results from 1st randomized clinical trial using high def. BLC equip.

Citizen's Petition* to re-classify BLC equipment: Stryker submits public comment, process ongoing

Budget Impact Model Publication in France applying AFU guidelines: concludes insignificant cost difference between WL and BLC use

Segment Trends

North America and Europe markets



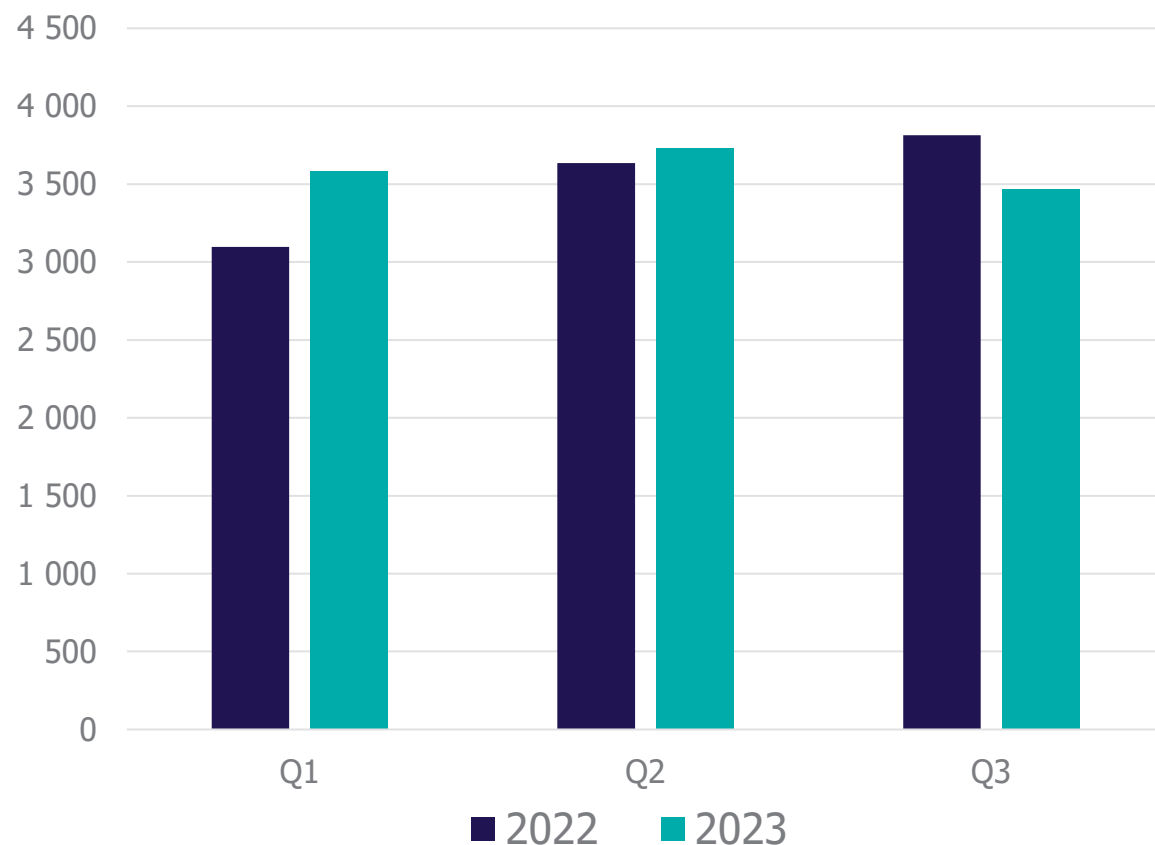
Loss of Flex in U.S. Pressured Growth, Europe Steady

Regional Unit Sales Year-Over-Year by Quarter

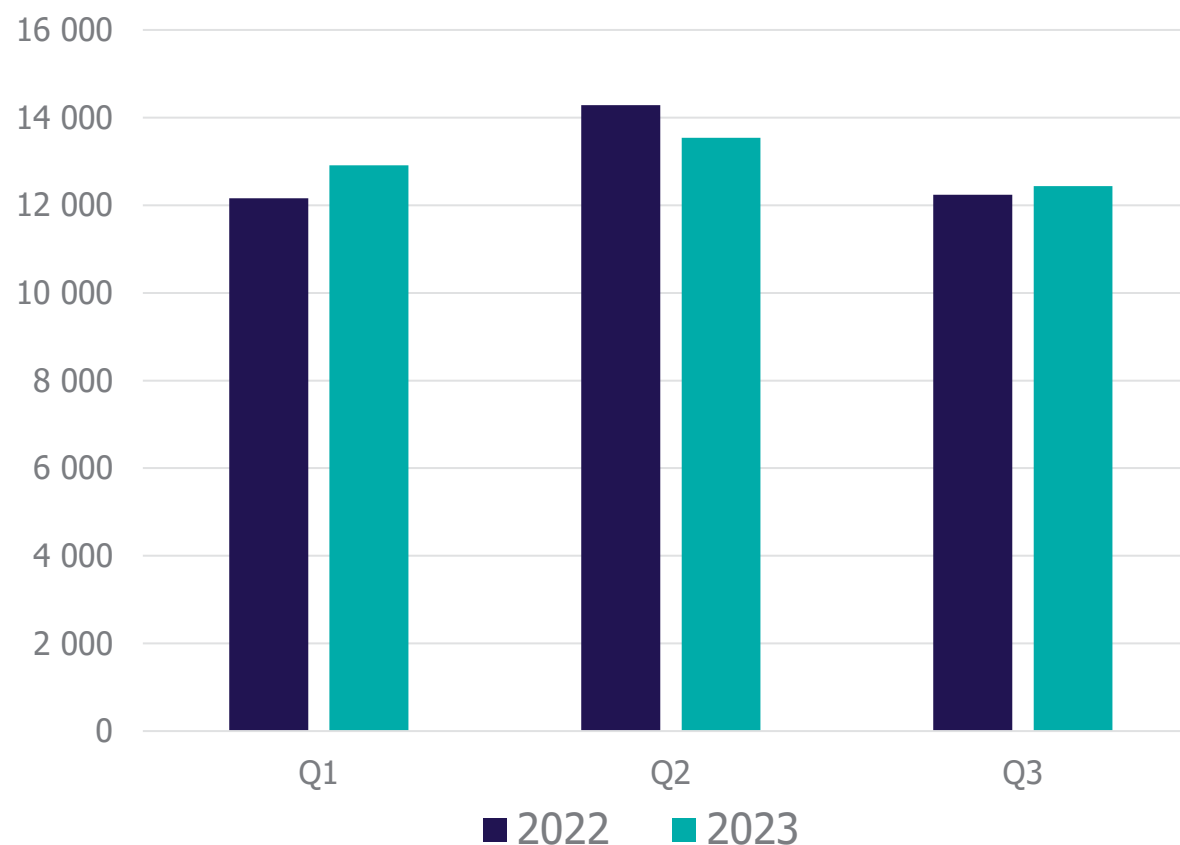


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North America



Europe



Q3 2023 Trends in North America

- **Q3 revenues increased 2%, in-market unit sales declined 9%;** Phase down of flexible BLC usage outweighed Cysview sales growth in the TURBT segment
- **Continued expansion of blue light tower installed base:** 15 new Saphira™ installations, 6 upgrades in Q3 (100+ quotes)
- **Demand for rigid blue light towers remains strong, BLC a key topic in urology:** Robust pipeline for new towers, Karl Storz extended promo through year-end, active AUA meeting, strong interest in Photocure's U.S. Bladder Cancer Registry (>3,000 patients)
- **Key initiatives to improve unit sales growth**
 - Increase Cysview kit usage in existing account base for TURBTs / Accelerate kit adoption of new accounts initiating use of blue light
 - Reactivate low users or inactive accounts through upgrades
 - Continue to expand BL penetration throughout the U.S. VA system leveraging VA BRAVO study data
 - Maintain as many of the 30 Flex accounts as possible for continued U.S. registry data collection and potential flex BLC reintroduction
- **Citizen's Petition for BLC reclassification**
 - Recent supportive public comment from Stryker Corp. backing BLC reclassification*
 - If FDA approved, would enable expedited pathway to expand the number of BLC equipment manufacturers in the U.S.
 - Flex tower discontinuation highlights the need for BLC reclassification



SUNA UroLogic Conference, October 26-29, 2023

* [FDA-2022-P-2644-0038_attachment_1.pdf](#)
Photocure – presentation of 3rd quarter 2023 results

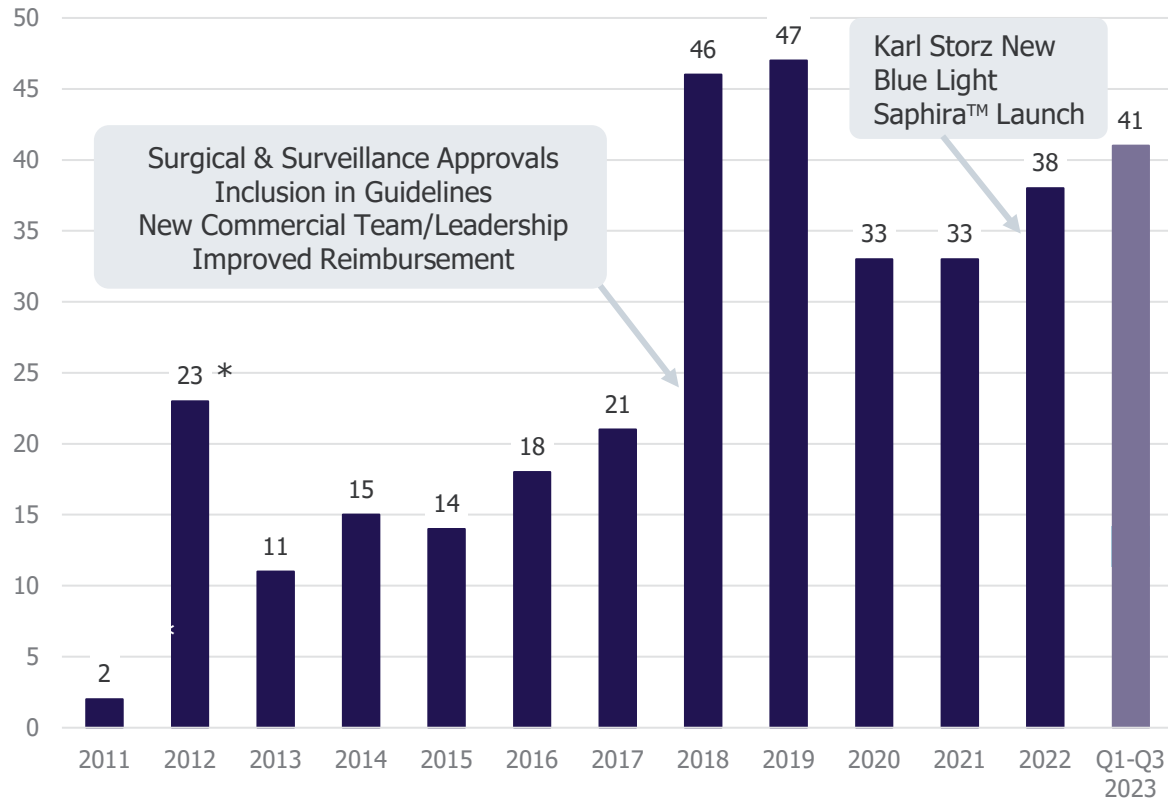
Saphira™ now 35% of rigid BLC installed base in U.S.



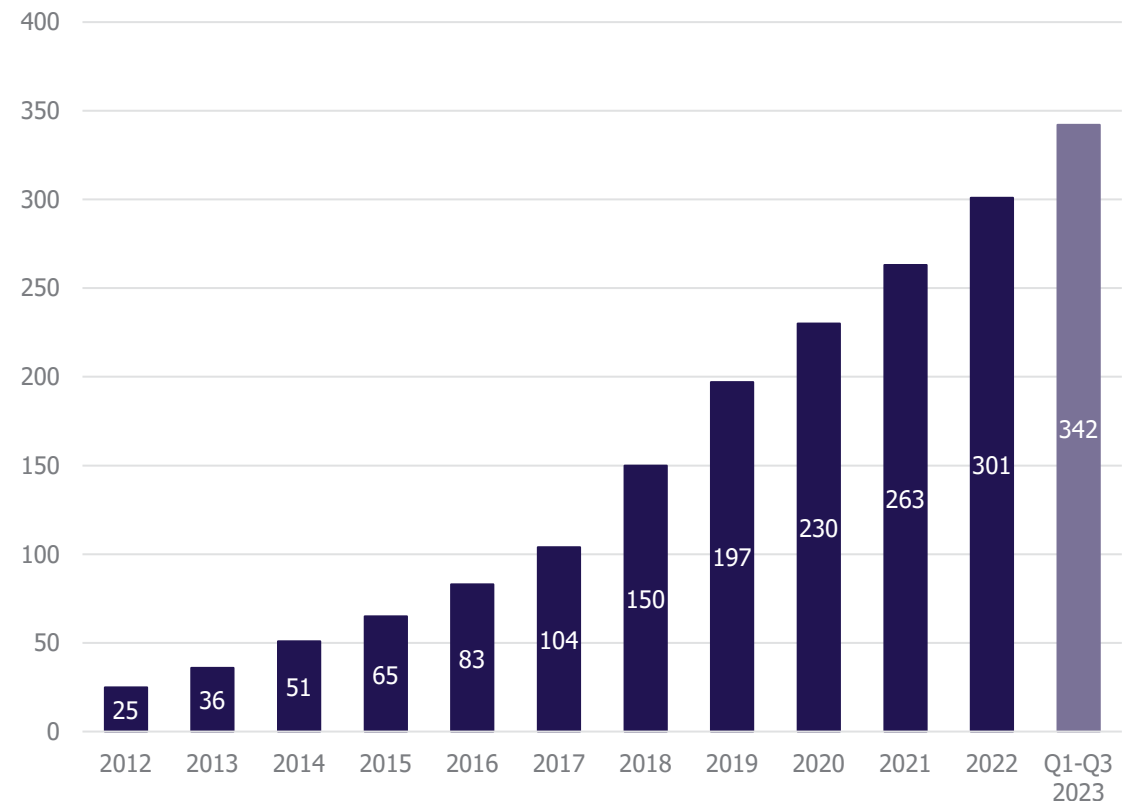
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21 installations in Q3 2023: 15 new account placements & 6 upgrades

Annual New BLC Tower Installations (Rigid Only)



Cumulative Installed Base in U.S. (Rigid Only)



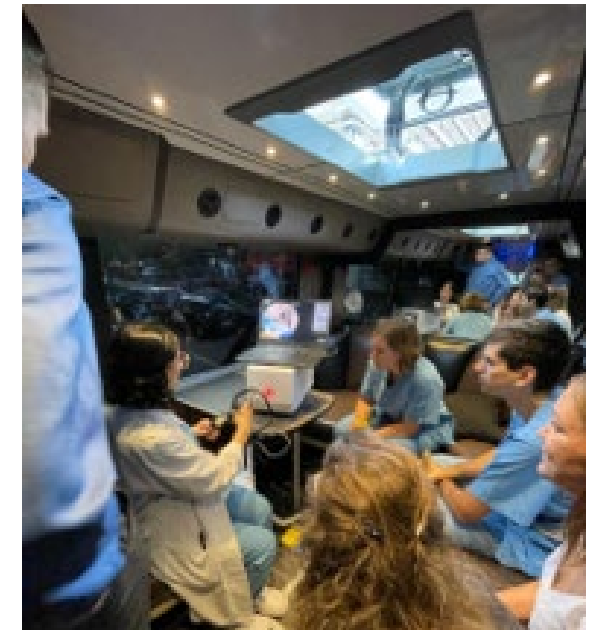
New Account Tower Installations
 Q4 2022: 31 installations (24 Rigid & 7 Flex)
 Q1 2023: 18 installations (Rigid only)
 Q2 2023: 8 installations (Rigid only)
 Q3 2023: 15 installations (Rigid only)

120 Saphira™ towers installed since Q3 2022 launch;
 71 New & 49 Upgrades

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

Q3 2023 Trends in Europe

- **Q3 revenues increased 17% year-over-year**, driven by the positive effect of price increases, continued growth in Germany and more broadly the DACH region, as well as a benefit from foreign exchange in the quarter. Unit sales volume increased 2% compared to the same period in 2022.
- **Blue light continues to gain traction in urology community;** Strong KOL support, high visibility at national urology congresses such as DGU; EAU guidelines strengthened with additional data in 2023
- **Photocure 2023 Bladder Cancer Bus Tour:** Successful roadshow in Q3 with 15 stops in Germany and Austria
- **Key initiatives to improve unit sales growth**
 - 1,400 TURBT-performing centers, approximately 50% have BL equipment
 - Actively targeting 590 hospitals/clinics; approximately 2/3 still underpenetrated
 - Continuing to execute image quality upgrades (130 YTD – 22% of targeted clinics)
 - 15 new blue light accounts opened YTD 2023; 27 Saphira™ POs pending





Significant progress with our partner Asieris

Hexvix China

Q3 & Recent News

**Phase III Trial
Enrollment
Completed**

**Primary Endpoint
Successfully Met;**

**Data presented
at SIU Congress
12 Oct 2023**

**Strong Results
($p < 0.0001$)**

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

Going forward

**Expect China NDA
Submission
Before YE 2023**

Cevira

Q3 & Recent News

**1st Non-Invasive
Candidate for
Cervical HSIL;
Phase III Results
China & Europe**

**Primary Endpoint
Successfully Met**

Going forward

**Positive Results
to be Presented
at Future Medical
Conference (TBD)**

**Asieris
Communication
with Regulatory
Authorities in
Coming Months**

**Photocure
eligible for
additional
milestones
& royalties upon
Asieris' regulatory
achievements,
market
authorizations,
& potential
sales**

Q3 Financials

Consolidated Income Statement

Third Quarter 2023



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<i>Amounts in NOK million</i>	Q3 '23	Q3 '22	Change	YTD '23	YTD '22	Change
Hexvix/Cysview Revenue	107.3	96.9	11%	329.1	278.2	18%
Other Revenue	0.3	9.8		29.0	10.8	
Total Revenue	107.5	106.8	1%	358.1	288.9	24%
Gross Profit	100.7	101.0	0%	337.9	271.9	24%
Operating Expenses excl BD	-96.7	-91.3	6%	-302.0	-266.7	13%
Business Development Expenses	-0.6	-5.0		-10.3	-13.0	
EBITDA – excluding BD	3.9	9.7		35.8	5.2	
EBITDA – including BD	3.3	4.7		25.6	-7.8	
Depreciation & Amortization	-7.2	-6.1		-20.2	-18.1	
EBIT	-3.9	-1.4		5.3	-25.9	
Net Financial Items	-4.8	-4.8		-12.1	-16.7	
Earnings before Tax	-8.7	-6.3		-6.8	-42.6	
Tax Expenses	3.8	-3.7		-5.4	-7.8	
Net earnings	-4.8	-9.9		-12.2	-50.4	

Revenue

- Q3 total revenue increased YoY 1%. Q3 2022 revenue was positively impacted by a USD 1.0 million milestone payment from Asieris
- Q3 Hexvix/Cysview revenue increased 11% vs. last year, driven by price and FX
 - Consolidated volume impacted negatively by the phase down of Cysview usage in the flexible BLC setting

Operating Expenses

- Q3 operating expenses excluding business development costs increased 6% YoY, mainly due to FX and inflation
- Operating expenses within business development projects relate to life cycle management for Hexvix/Cysview

EBITDA

- Q3 EBITDA including business development expenses NOK 3.3 million (NOK 3.9 million ex-BD expense)

Net Financial Items

- Includes Ipsen earn-out payments

Segment Performance Third Quarter 2023



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North America Segment

<i>Amounts in NOK million</i>	Q3 '23	Q3 '22	Change	YTD '23	YTD '22	Change
Total revenues	43.6	42.9	2%	132.0	112.1	28%
Gross profit	42.2	41.4	2%	127.7	108.5	28%
<i>% of revenue</i>	<i>97%</i>	<i>97%</i>		<i>97%</i>	<i>97%</i>	
Direct costs	-34.2	-38.8	-12%	-122.6	-116.9	13%
Contribution ⁽¹⁾	8.0	2.7		5.2	-8.5	
EBITDA, excl BD	-2.2	-7.1		-24.2	-35.6	
<i>% of revenue</i>	<i>-5%</i>	<i>-17%</i>		<i>-18%</i>	<i>-32%</i>	

- Q3 revenue growth 2% driven by price increases and FX, partially offset by phase down of Cysview usage in the flexible BLC setting
 - In-market unit sales decreased 9%, USD appreciated 5%, price increase 5% in US
- Q3 direct costs decreased, despite negative impact of FX
- Contribution improved NOK 5.3 million YoY driven by cost containment

Europe Segment

<i>Amounts in NOK million</i>	Q3 '23	Q3 '22	Change	YTD '23	YTD '22	Change
Total revenues	63.4	54.0	17%	196.7	165.6	19%
Gross profit	58.2	50.0	17%	181.9	152.9	20%
<i>% of revenue</i>	<i>92%</i>	<i>92%</i>		<i>92%</i>	<i>92%</i>	
Direct costs	-29.1	-25.6	14%	-85.7	-73.5	17%
Contribution ⁽¹⁾	29.1	24.3		96.3	79.5	
EBITDA, excl BD	10.4	7.2		43.5	31.3	
<i>% of revenue</i>	<i>16%</i>	<i>13%</i>		<i>22%</i>	<i>19%</i>	

- Q3 revenue increased 17% YoY
 - In-market unit sales increased 2% YoY, EUR appreciated 13%, price increases across several countries contributed remaining 2%
- Expenses were driven by negative impact of FX
- Contribution improved NOK 4.8 million YoY, driven by higher revenue

Cash Flow & Balance Sheet Third Quarter 2023

<i>Amounts in NOK million</i>	Q3 '23	Q3 '22	YTD '23	YTD '22
Operations Cash Flow	8.7	21.3	28.7	-2.7
Earnings before tax	-8.7	-6.3	-6.8	-42.6
Depreciation & amortization	7.2	6.1	20.2	18.1
Working capital	1.8	5.6	-10.0	-14.6
Other	8.4	15.9	25.2	36.2
Investments Cash Flow	-2.5	-0.3	-1.8	-2.3
Financing Cash Flow	-10.0	-10.2	-39.9	-34.0
Net Change in Cash	-3.9	10.8	-13.0	-39.0

<i>Amounts in NOK million</i>	30.09.23	31.12.22
Non-current assets	347.7	360.8
Inventory & receivables	102.8	90.2
Cash & short-term deposits	255.1	268.1
Equity	468.9	462.7
Long-term liabilities	157.3	167.1
Current liabilities	79.3	89.2
Total balance	705.6	719.0

Cash Flow

- Net cash flow from operations in Q3 NOK 8.7 million, driven by EBITDA adjusted for non-cash cost items
- Net investment cash flow includes capitalization of certain medical expenses in the U.S.
- Net cash flow from financing NOK -10.0 million relates mainly to earnout payments to Ipsen
 - Term loan was fully repaid in Q2
- Net cash flow in Q3 NOK -3.9 million, cash balance end of Q3 NOK 255.1 million

Financial position

- Non-current assets include intangibles and goodwill from Ipsen transaction totaling NOK 260.7 million
- Long-term liabilities includes deferred Ipsen earnout totaling NOK 128.7 million
- Equity NOK 468.9 million, 66% of total assets

Summary



Summary of Q3 results

- 11% revenue growth / -1% unit sales growth YoY; several initiatives to reaccelerate unit sales momentum
- 21 Saphira™ towers installed in U.S. (15 new, 6 upgrades)
- Saphira™ now 35% of rigid towers in U.S.; Strong pipeline for HD BLC equipment remains, 100+ quotes issued
- EBITDA of NOK 3.3 million (NOK 3.9 million excl. BD); Commercial business EBITDA-positive in the quarter
- Cash balance strong at NOK 255 million; no term debt
- BLC awareness continues to rise in urology community, KOL support, and equipment/image quality upgrades
- Refined guidance; continued challenges from flex phase-down, staffing shortages, capital budget pressures
- Stryker submits public comment supporting Karl Storz's Citizen's Petition; Potential re-classification of BLC equipment could "unlock" the market for Cysview in the U.S.

Anticipated Milestones & Corporate Objectives



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- 2023 Guidance: 65-75 new Saphira™ blue light tower installations assuming delivery of an anticipated large PO in Q4; consolidated product revenue growth in the range of 17-20% including the impact of FX and the ongoing flexible BLC phase down; and positive EBITDA anticipated in the range of NOK 45-50 million excluding BD spending
- Continue to grow the base of rigid blue light towers in North America, upgrade BLC® image quality throughout Europe, and pursue strategy to establish a durable solution for flexible BLC equipment globally
- 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
- Continue to geographically expand commercial business by penetrating untapped European markets, and through additional Hexvix® licensing agreements ROW
- Present/publish additional data from patient registries and other studies on the use of BLC® with Hexvix/ Cysview
- Continued progress for Asieris Assets: Cevira Phase III data expected at upcoming medical congress, potential for Hexvix regulatory submission in China end of 2023/Cevira in 2024, anticipated milestone payments/future royalties

Leading change in bladder cancer

Q&A