

FUTURE PROOF HEALTHCARE

A sustainable healthcare for a new generation

Presentation Q4(21)

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Headquarters, Marketing and demo lab, Consumable production in Uppsala

Q-linea 4th quarter



Q-linea is developing disruptive solutions for faster infectious disease diagnostics, first product targeting sepsis

173 employees & consultants at year end

Achieved CE-IVD for first application for ASTar, May 4th 2021

Very strong results from commercial evaluation of ASTar

Thermo Fisher Scientific has presented ASTar at two trade shows (KMIS, RICA) with good response

Strong interest from the market

Discussions with potential partners for Podler®

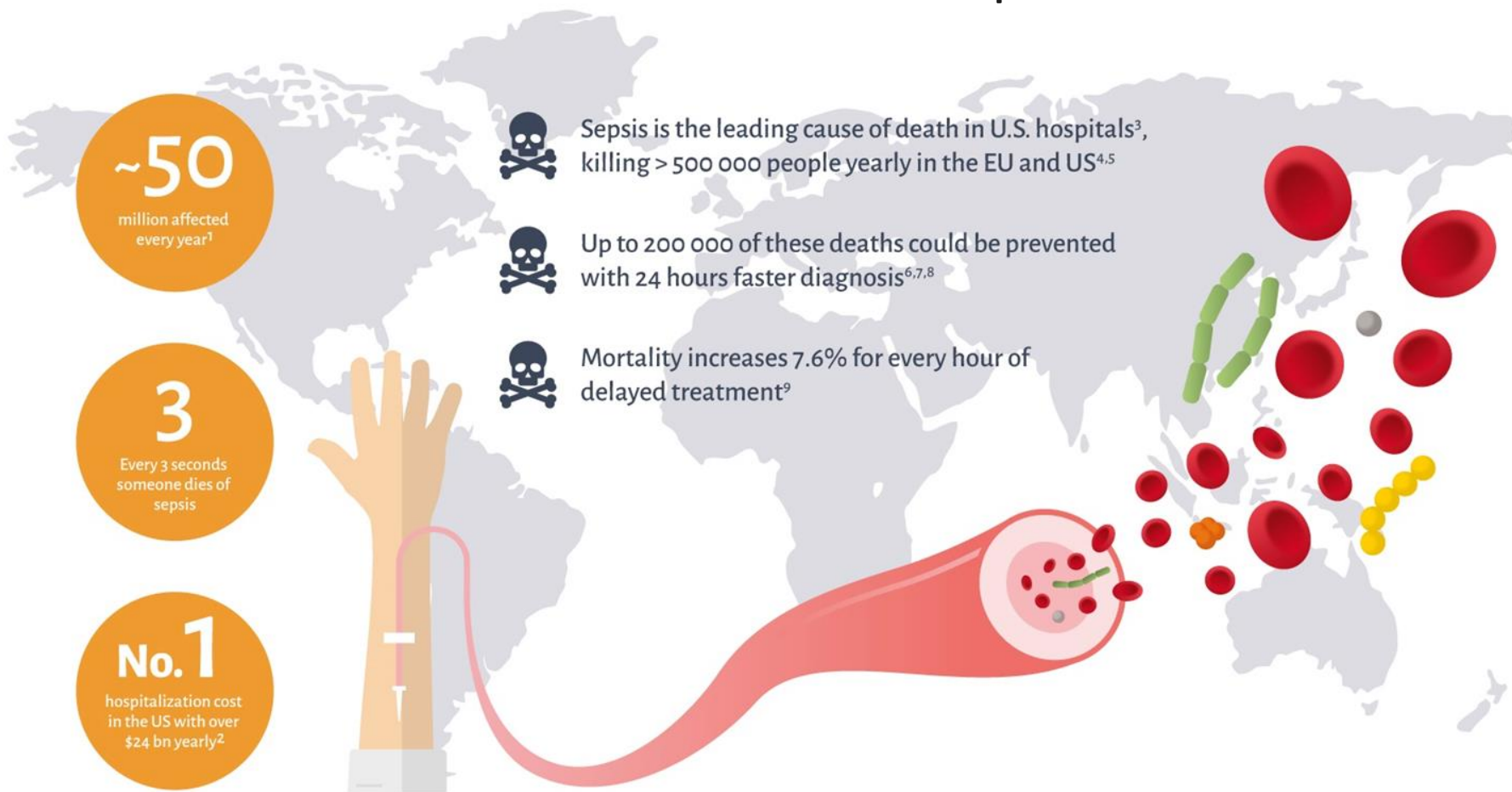
Lead product ASTar®



Q-LINEA 

Sepsis – a global health crisis

Time to correct treatment critical for patient outcome



Why is improved infectious disease diagnostics important?

Sepsis

Leading cause of death in U.S. hospitals¹⁾
#1 hospitalization cost in the US with over \$24bn yearly³⁾

Kills >500,000 people yearly in the EU and US²⁾
Every 3 seconds someone dies of sepsis worldwide

~50% of all patients receive inappropriate treatment
~20% dies before current diagnostic provide results

Rapid diagnostics could reduce mortality with up to 40%⁴⁾

AMR

Antimicrobial Resistance

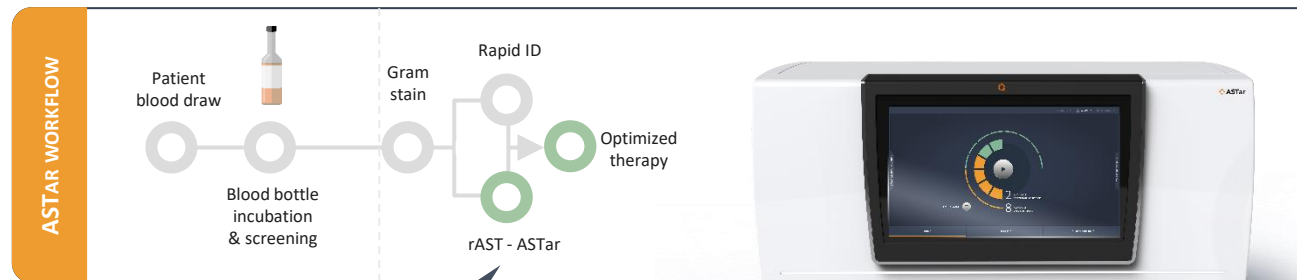
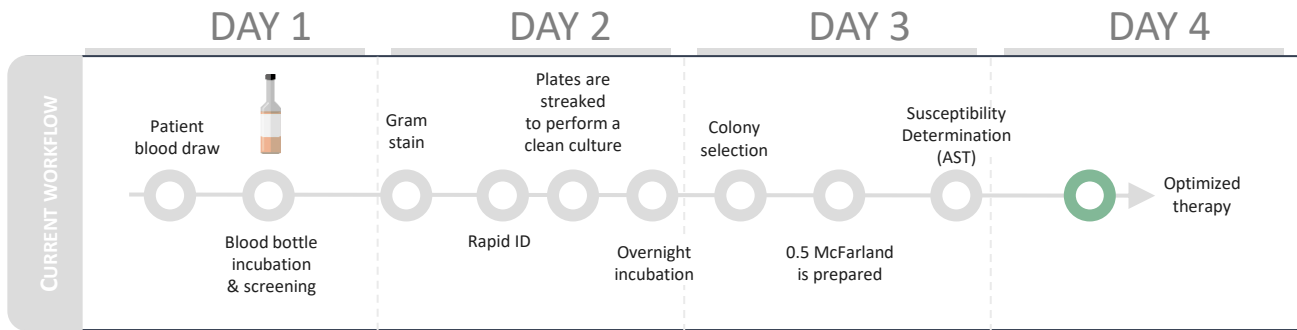
Has been presented as
“The biggest threat to mankind”

Rapid diagnostics would reduce unnecessary prescription
>65 % of all prescribed antibiotics for respiratory issues are unnecessary⁵⁾

Deaths due to AMR⁵⁾
In 2016, ~700 000 died
In 2050, 10 000 000 are expected to die if we do not act now

Source: 1. JAMA. 2014;312(1):90-92. 2. Clinical Infectious Diseases. 2014;51(12):2133-2138. 3. <https://doi.org/10.1093/cid/ciy342>, Fleischmann et al, Am J Respir Crit Care Med. 2016 Feb 1;193(3):259-72, Company estimates 4. <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb204-Most-Expensive-Hospital-Conditions.pdf>. 5. Patel et al, J Clin Microbiol. 2017 Jan; 55(1): 60-67., ECCMID 2017, poster OS1033, Andreassen et al. Cost-effectiveness of MALDI-TOF and rapid antimicrobial susceptibility testing for high-risk patients, Huang et al. Clin Infect Dis. 2013 Nov; 57(9): 1237-45. 5. Tackling drug-resistant infections: Final report and recommendations. Review on Antimicrobial Resistance. Web. 2016

Rapid AST & a broad antimicrobial panel matters: ASTar can provide up to 48 hours faster actionable results



A broad panel, >25 antibiotics
Enable start of AST AND ID at
the same time

Time to Actionable results is what matters for septic patients

Health economic benefits of 24 hour faster diagnostics

Lower mortality

Up to 40%
lower mortality rates¹⁾

Less pressure for resistance and superinfections

Up to 25%
reduction of *C. difficile*
infections²⁾

Cost savings

~\$2,500 – \$20,000
cost savings per patient³⁾



ASTar can provide **up to 48 hours** faster diagnostics

Source: 1) Patel et al, *J Clin Microbiol.* 2017 Jan; 55(1): 60–67., ECCMID 2017, poster OS1033, Andreassen et al. Cost-effectiveness of MALDI-TOF and rapid antimicrobial susceptibility testing for high-risk patients, Huang et al. *Clin Infect Dis.* 2013 Nov; 57(9): 1237-45. 2) Fridkin et al, *MMWR*, 2014;63(9), 194-200. 3) Perez et al, *Arch Pathol Lab Med* 137:1247-1254, 2013, Perez et al *J Infect.* 2014 Sep;69(3):216-25, 2014, Bauer et al *Clin Infect Dis* 51:1074-1080, 2010.) Patel et al, *J Clin Microbiol.* 2017 Jan; 55(1): 60–67.

AStar – a platform designed to save lifetimes

Developed together with our future customers

Easy to use

- **Fully automated**
- ~2 min hands-on time
- Load-and go workflow

Fast

- Results in ~6 hours
- **High throughput**
- 12 simultaneous samples



Comprehensive

- **Large antibiotic panel**
- Long concentration ranges
- Fastidious and non-fastidious bacteria
- Support additional samples (*e.g.* urine)

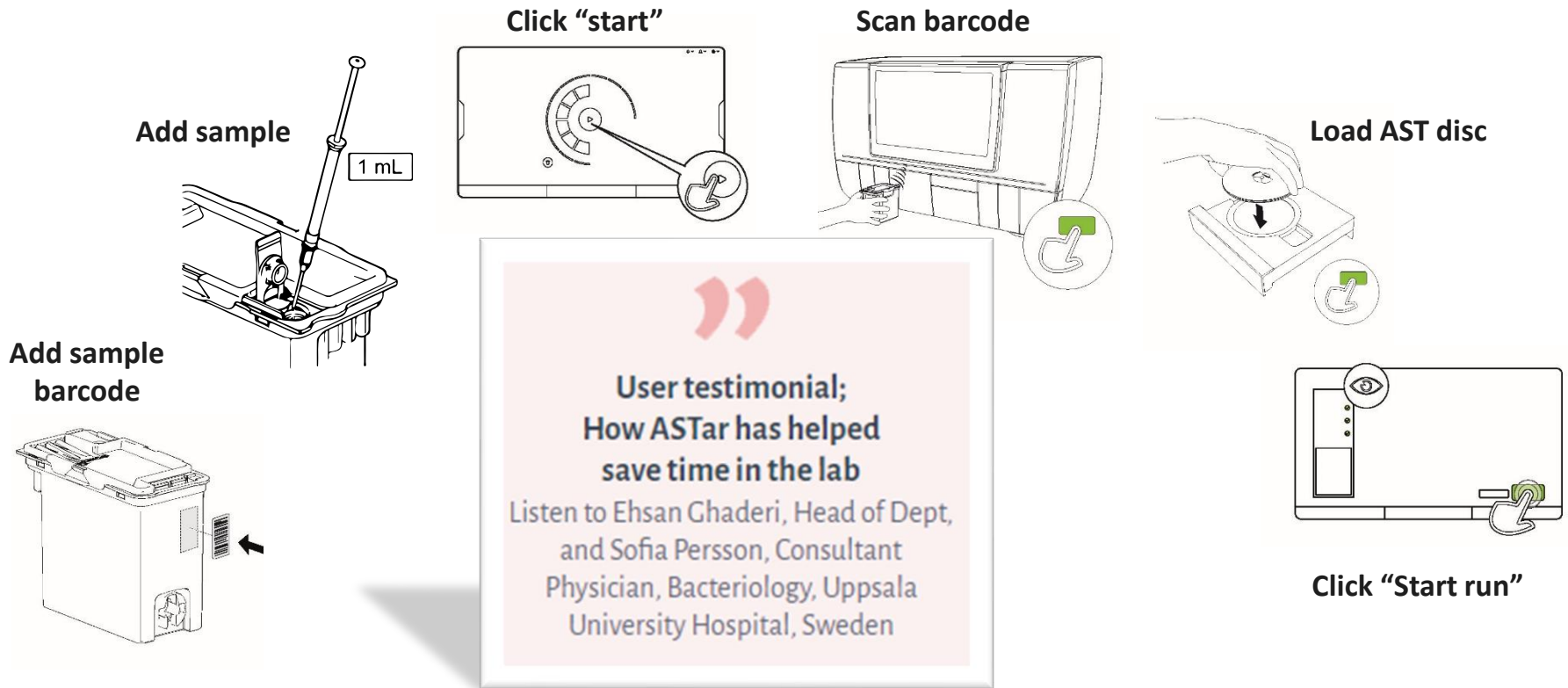
Accurate

- **True MIC results**
- High reproducibility

Easy to use

ASTar enables anyone at the lab to load sample anytime and enables lab personnel to do more in less time

User friendly
& 24/7 availability






Source: Company information and webpage

AS^Tar provides excellent performance

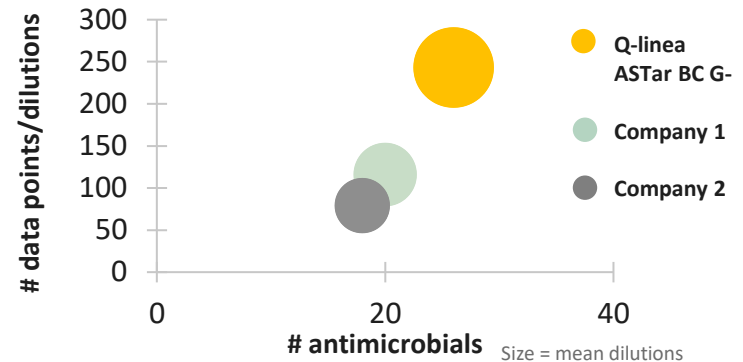
Broadest panel
enabling
actionable results

Excellent and accurate data from the CE-IVD clinical study

FDA and ISO requirements ^{1,2)}		
Essential agreement = Same MIC value as reference		
FDA	ISO	Q-LINEA 
89.9%	90%	94.7% ³
Categorical agreement = Correct treatment recommendation		
FDA	ISO	Q-LINEA 
89.9%	90%	97.6% ³
Reproducibility		
FDA	ISO	Q-LINEA 
95%	95%	99.6% ³

The AS^Tar[®] Instrument and AS^Tar[®] BC G- Kit offer the **broadest combination of antimicrobials and dilution ranges** in a single analysis for Gram-negative bacteria ⁶. The analysis also **delivers true MIC results**.

Coverage BC G- : comparing antimicrobials, datapoints and mean datapoints per antimicrobial



Source: 1) ISO 20776-2, Clinical laboratory testing and in vitro diagnostic test systems — Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices: - Part 2: Evaluation of performance of antimicrobial susceptibility test devices 2) Guidance for Industry and FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems, August 28, 2009, FDA document number 631.3) Company results from CE-IVD clinical study for BC G-, Gram negative antibiotic panel 2020-05-04 6) Based on commercially available systems market overview May 2021

High throughput and flexible solution

Our ambition was the most user friendly and capable system

High throughput & flexible



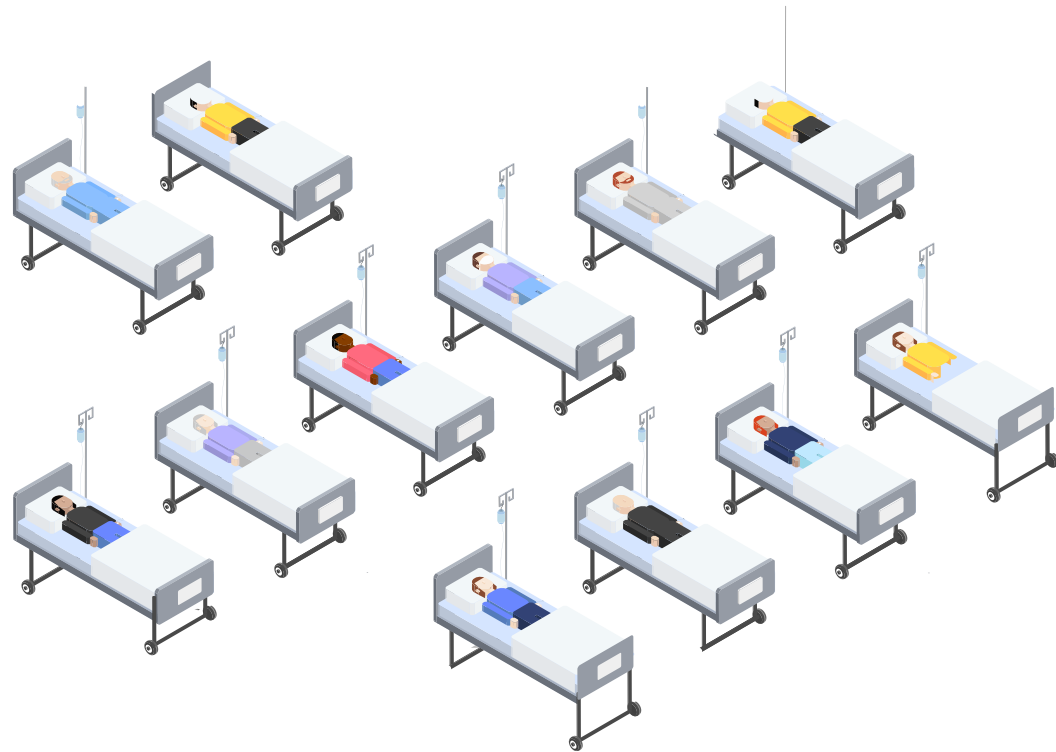
Fully automatic Semi automatic



Consumables stored at room temp and a small insert at -20°C.

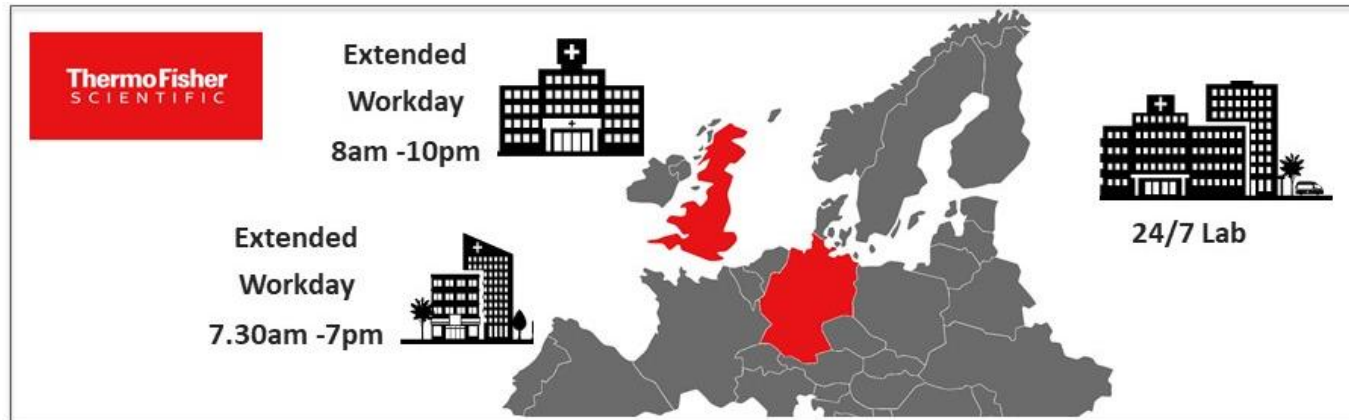
Compatible with small and large (e.g. urine) sample volumes, and to run isolates separately

Up to 12 patient samples in parallel



Excellent results from extensive commercial evaluation

AStar performed very well with great customer feedback



Evaluation performed by Thermo Fisher Scientific™ with support from Q-linea

Customer sites performed AStar testing on G- BC+ patient samples in parallel to their current testing

Almost 500 determinations using routine clinical samples

Comparison against Sensititre™ (CE claim) and In House Methos (Vitek® and Multipoint)

>96,6% Essential agreement across all sites compared to Sensititre

Database covered 98,7% of all G- organisms seen

System was robust. One service intervention across all sites during evaluation

Key highlights fourth quarter

Strong results from commercial evaluation performed by Q-linea in Sweden

Evaluation performed at a Swedish Regional Hospital

Overall Essential Agreement (EA) = 96,3%

The study included approximately 30 patients

Patient samples included both non-fastidious and fastidious bacteria

AStar outperformed traditional care by providing same shift results

AStar enabled rapid escalation on critically ill patient > 18 hours faster

Overall, a success hitting all pre-determined evaluation target

We are now discussion next commercial steps with customer

Key highlights fourth quarter

Patient – case report Swedish evaluation, ASTar makes a difference...

Case report

- Patient at surgical department on empiric treatment Piperacillin/tazobactam
- Change of antibiotics earliest 10 am day 2 with Vitek 2 (Standard AST)
- ASTar results at least **18 h earlier** than Standard AST with MIC results from 13 additional antibiotics
- Resistant against initial, empiric treatment

Timeline

Day 1



Key highlights fourth quarter

US clinical study entered final stage

Prospective study started

Three US hospitals included in the prospective study

Enrollment started in December

Slight delays initially because of Covid

After period end

The preparation of the 510k application started

Initial data review looks strong, we aim to further broaden the kit

Goal is to submit the 510k application during the spring

Key highlights fourth quarter

Active presentation of ASTar by Thermo Fisher Scientific

Since launch in October an active period with customer visits & trade shows started

Thermo Fisher Scientific presented ASTar on two trade shows

- KMIS (Virtual) 2-4 Dec
- RICA Paris 13-14 Dec

Strong interest from potential customers



Key highlights fourth quarter

Strong interest from the market but long sales processes

Thermo Fisher Scientific is actively marketing ASTar with a large team

Strong interest from customers

Large and continuously growing sales funnel

Several evaluations ongoing and are in the planning

Some evaluations have been delayed because of Covid

The situation steadily improves, but with regional differences

The capacity to perform evaluations is currently the limiting factor

Q-linea is investigation on how to provide additional support

The processes with tenders indicates that 2022 will be a back-loaded year regarding sales, but overall customer interest indicates that we look at the future with optimism

Key highlights after period end

ASTar's value proposition further strengthen

ASTar already provided the broadest combination of antimicrobials and dilution ranges in a single analysis for Gram-negative bacteria.

Our goal has always been to enable as many patients as possible to receive faster time to actionable results.

In January the ASTar panel further increased with.

- 18 combinations of bacteria and antibiotics

- Cover 222 different combination in total

- 23 antibiotics for non-fastidious bacteria and 6 antibiotics for fastidious bacteria

ASTar further support analysis of 9 different blood culture bottles

- Cover most commonly used bottles and enables a broad customer approach

ASTar support inclusion of positive blood culture bottle up to 16 hours after positivity

- Increased utilization compared to other rapid AST solutions

The effects of the Corona pandemic on Q-linea

Moving back to normal operation

Finally, we are now all moving back to the new normal after the pandemic

Our conclusion is that Q-linea and its personnel has managed the pandemic in a good way

- No identified spread within the company

- Rapid follow up and infection tracking to minimize further spreading

- Provided help in analysing Covid tests at the Uppsala University hospital

Future possible effects of the Corona pandemic

Depending on the development of the pandemic the primary risk is reduced access to customers and to perform customer evaluations

Shortage of components are still a risk, but Q-linea has provided long term orders of components to minimize the problem

Expense levels and financing strategy linked to possible delays in company activities.

We will follow the development carefully and although we see a positive development it is not over yet with new strains that may cause future escalation.

Income statement fourth quarter

Net sales in the fourth quarter amounted to SEK 3.9 million (0.0).

Goods that have been expensed in the fourth amounted SEK -3.4 (0) million.

Operating result totalled SEK -51.6 million (-57.1).

The company reported a loss after tax of SEK -51.0 million (-56.6).

Earnings per share, before and after dilution amounted to SEK -1.75 (-2.10).

Figures in parentheses refer to the outcome for the corresponding period in the preceding year with respect to earnings and cash flow and to the closing balance in the preceding financial year with respect to the balance sheet.

Source: Company information.

Balance sheet at the end of fourth quarter

Cash and cash equivalents amounted to SEK 15.1 million (10.1)

Short-term investments in fixed-income funds SEK 91,2 million (165,7) and the current portion of non-current assets (listed bonds) SEK 59.7 million (131.0).

Non-current assets, listed bonds SEK 181.8 million (24.4).

Inventories amounted SEK 28.6 million (12.4), includes a write-off of total SEK -4,7 (0) million.

Source: Company information.

Figures in parentheses refer to the outcome for the corresponding period in the preceding year with respect to earnings and cash flow and to the closing balance in the preceding financial year with respect to the balance sheet.

Cash flow statement fourth quarter

Cash flow from operating activities SEK -90.9 million (-76.7).

Increase in cash outflow from operating activities mainly due to changes in the working capital compared to the same quarter last year.

Cash flow from investing activities SEK 84.4 million (69.1).

Net divestment of Short-term interest funds and investments in listed bonds. Investments in mainly production equipment amounted SEK 6.0 (1.0) million

Cash flow from financing activities SEK -40 thousand (-80).

Repayment of loans

Cash and cash equivalents, Short term investments and listed bonds at the end of second quarter amounted **SEK 347.8 million** (331.3). The Board's assessment is that the existing working capital, as of 31 December 2021, **is sufficient to cover the Company's needs for at least the next 12 months.**

Source: Company information.

Figures in parentheses refer to the outcome for the corresponding period in the preceding year with respect to earnings and cash flow and to the closing balance in the preceding financial year with respect to the balance sheet.

Looking forward to an exciting continuation of 2022



Q-linea wants to contribute to a healthier society by future-proofing a new generation of healthcare professionals, labs and hospitals.

Thank you