

# FUTURE PROOF HEALTHCARE

A sustainable healthcare for a new generation

## Presentation Q3(21)

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# Q-linea 3<sup>rd</sup> quarter



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

160 employees & consultants at third quarter end

**Achieved CE-IVD for first application for ASTar, May 4<sup>th</sup> 2021**

**Very strong results from commercial evaluation of ASTar**

**Strong development of the portable culturing technology**

Development continued and contract manufacturers currently being selected

## 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. hospitals<sup>1)</sup>  
#1 hospitalization cost in the US with over \$24bn yearly<sup>3)</sup>

Kills >500,000 people yearly in the EU and US<sup>2)</sup>  
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%<sup>4)</sup>**

## AMR

Antimicrobial Resistance

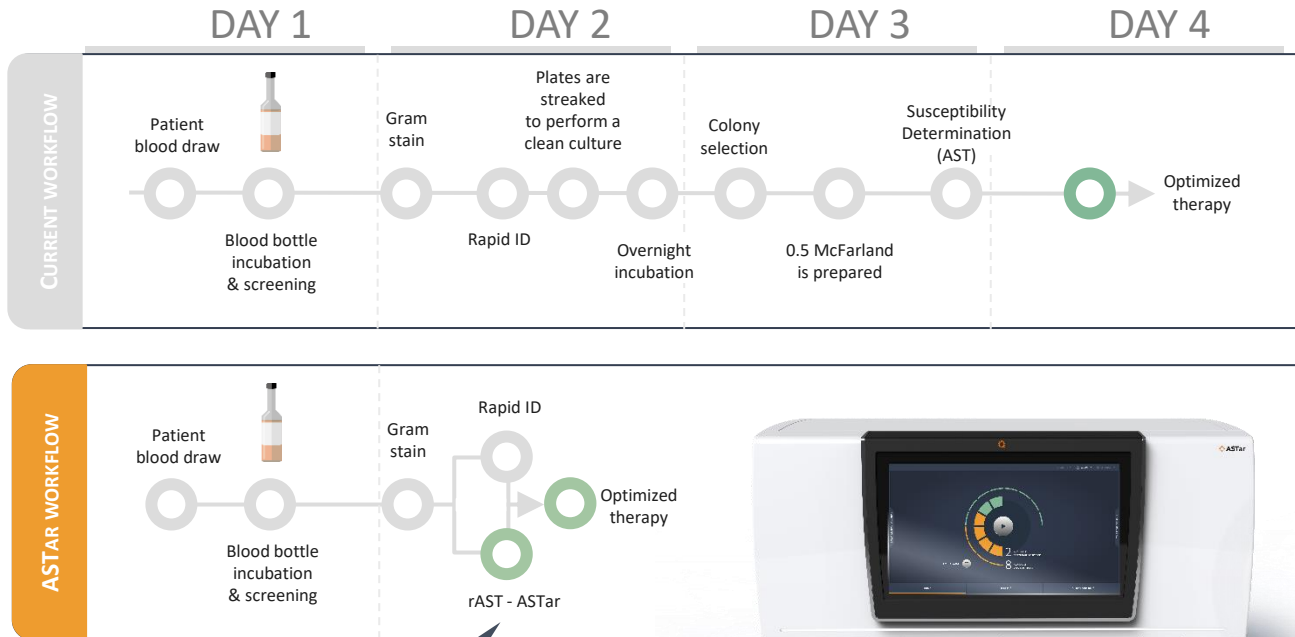
Has been presented as  
**“The biggest threat to mankind”**

**Rapid diagnostics would reduce unnecessary prescription**  
>65 % of all prescribed antibiotics for respiratory issues are unnecessary<sup>5)</sup>

Deaths due to AMR<sup>5)</sup>  
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 ciy342, <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 3. <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb204-Most-Expensive-Hospital-Conditions.pdf>. 4. 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 40 hours faster actionable results



Time to  
**Actionable**  
results is  
what  
matters for  
septic  
patients

A broad panel, >20 antibiotics  
Enable start of AST AND ID at  
the same time



# Health economic benefits of 24 hour faster diagnostics

## Lower mortality

Up to 40%  
lower mortality rates<sup>1)</sup>

## Less pressure for resistance and superinfections

Up to 25%  
reduction of *C. difficile*  
infections<sup>2)</sup>

## Cost savings

~\$2,500 – \$20,000  
cost savings per patient<sup>3)</sup>



ASTar can provide **24-40** hour 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

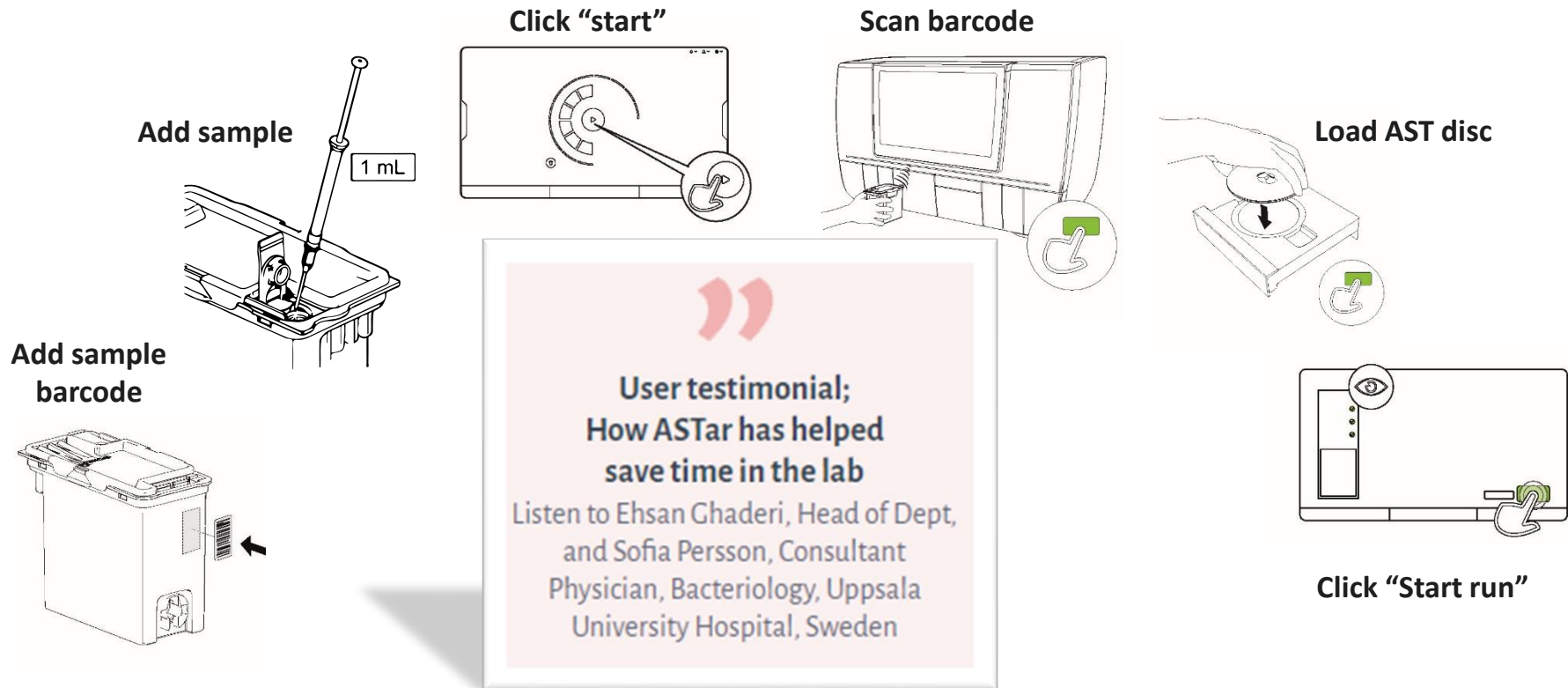
- **True MIC results**
- High reproducibility



# 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

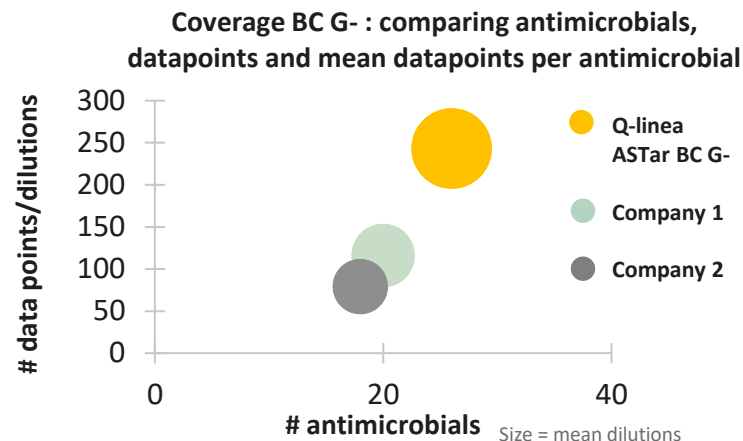
# AStar provides excellent performance

Broad panel  
enabling  
actionable results

Excellent and accurate data from the CE-IVD clinical study

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

The AStar® Instrument and AStar® BC G- Kit offer the **broadest combination of antimicrobials and dilution ranges** in a single analysis for Gram-negative bacteria <sup>6</sup>. The analysis also **delivers true MIC results**.



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

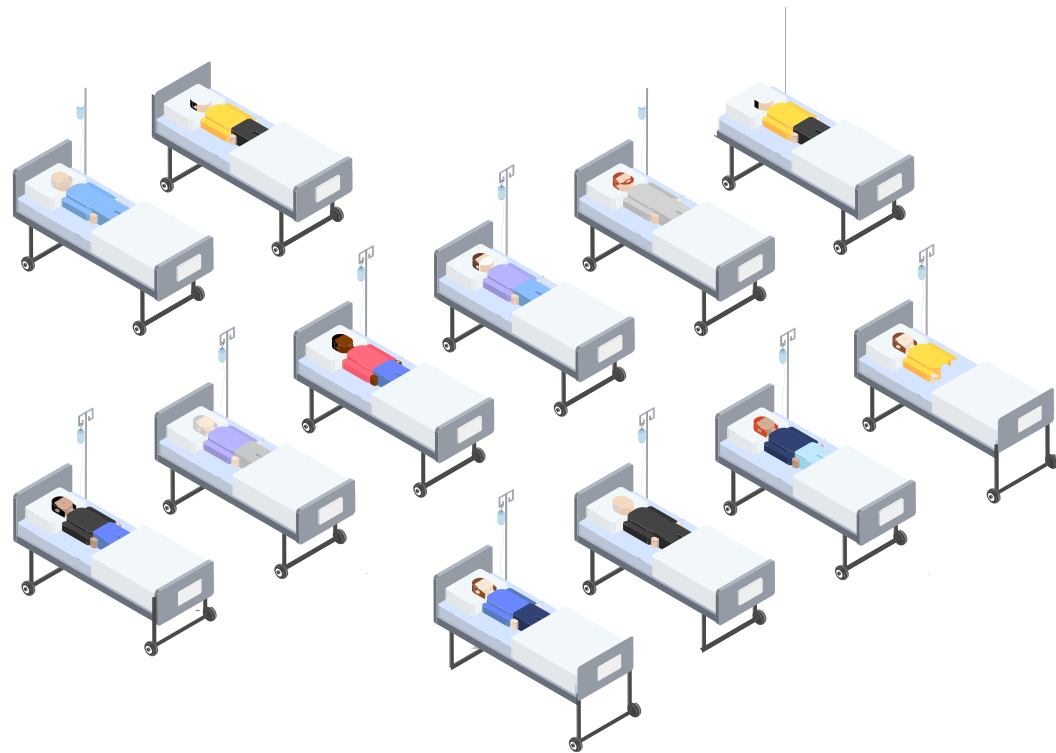
Our ambition was the most user friendly and capable system

High throughput & flexible

Up to 12 patient samples in parallel



=



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

# Key highlights third quarter

## **Commercial evaluation performed during the quarter with excellent results**

Thermo Fisher Scientific™ performed the evaluation supported by Q-linea

Several European sites selected by Thermo Fisher Scientific to evaluate ASTar

All results were compared to reference measurements and current in-house method

## **Results from the study were excellent in all key aspects:**

System stability

Performance and

Customer feedback

# Key highlights third quarter

## Continued development of the portable culture device

Fully functional prototypes has been extensively tested  
Average time to positivity is one hour or more faster  
compared to traditional culture cabinet

– And you also save the entire travel time...

## Selection of contract manufacturer ongoing

Several potential contract manufacturer have been  
evaluated and selection is currently ongoing.

## US customer evaluation

Market study including 23 hospitals completed  
Strong feedback received with a clear value for patients



# Key highlights after the period

## **US clinical study for ASTar enters next phase**

The reproducibility was started at three Swedish sites in October

Last phase is to start prospective part of the study in US hospitals

# Key highlights after the period

**Thermo Fisher Scientific launched ASTar in Europe 7 October<sup>1</sup>**



**And Q-linea signed first evaluation contract for Sweden 15 October**

1). <https://www.prnewswire.co.uk/news-releases/thermo-fisher-scientific-and-q-linea-launch-astar-system-a-rapid-antimicrobial-susceptibility-testing-system-835609700.html>



# 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 University hospital

## **Future possible effects of the Corona pandemic**

Depending on the development of the pandemic there is still a risk for the overall timeline for the US clinical study

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 third quarter

Net sales in the third quarter amounted to SEK 1.1 million (0.0).

Cost of Goods Sold and production costs SEK -3.1 (0) million

Gross margin SEK -2,0 (0) million ; -182 (0) %

Operating result totalled SEK -50.0 million (-50.0).

The company reported a loss after tax of SEK -49.1 million (-48.7).

Earnings per share, before and after dilution amounted to SEK -1.68 (-1.80).

*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 third quarter

Cash and cash equivalents amounted to SEK 21.6 million (10.1)

Short-term investments in fixed-income funds SEK 181,2 million (165,7) and the current portion of non-current assets (listed bonds) SEK 26.3 million (131.0).

Non-current assets, listed bonds SEK 215.4 million (24.4).

Inventories amounted SEK 23.4 million (12.4).

*includes a write off of total SEK -2,7 (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 third quarter

Cash flow from operating activities SEK -63.0 million (-46.7).

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

Cash flow from investing activities SEK 36.5 million (27.3).

Net divestment of Short-term interest funds and investments in listed bonds.

Cash flow from financing activities SEK -53 thousand (-708).

Repayment of loans

Cash and cash equivalents, Short term investments and listed bonds at the end of second quarter amounted **SEK 444.5 million** (331.3). The Board's assessment is that the existing working capital, as of 30 September 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 2021



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

## Thank you