

FUTURE PROOF HEALTHCARE

A sustainable healthcare for a new generation

Presentation Q2(21)

Jonas Jarvius, CEO
Anders Lundin, CFO/IR



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Headquarters, Marketing and demo lab, Consumable production in Uppsala

Q-linea 2nd quarter



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

Achieved CE-IVD for first application for AS^{Tar}, May 4th 2021

US clinical study started in June

Commercial evaluation at potential customers ongoing

150 employees & consultants at first quarter end

Strong development of the portable culturing technology

First completely autonomous prototypes evaluated with very strong results

Lead product AS^{Tar}®



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. 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

AS*Tar* – 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)

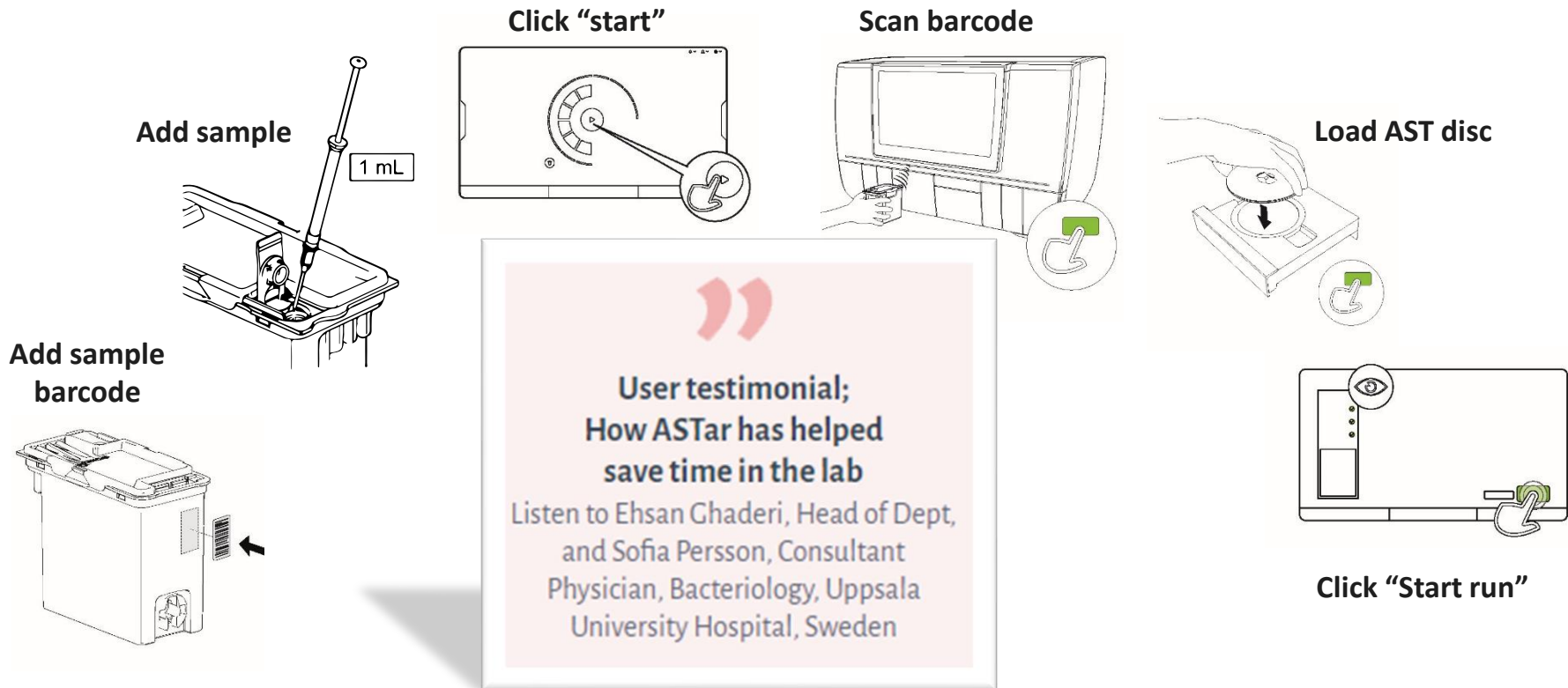
Accurate

- **True MIC results**
- High reproducibility

Full automation matters:

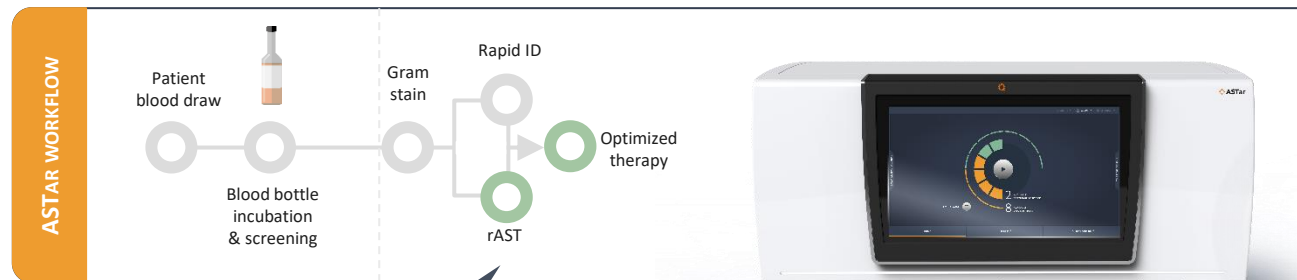
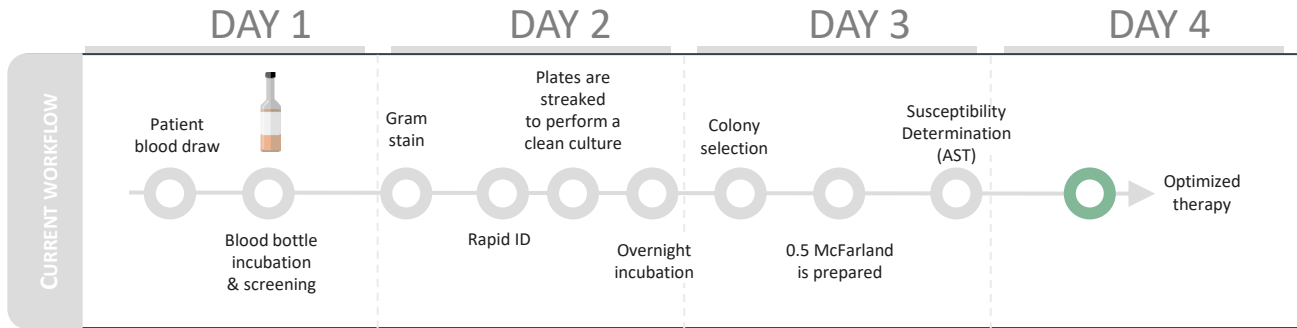
ASTar enables anyone at the lab to load sample anytime

ASTar enables lab personnel to do more in less time



Source: Company information and webpage

Rapid AST & a broad antimicrobial panel matters: ASTar can provide up to 40 hours faster actionable results



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

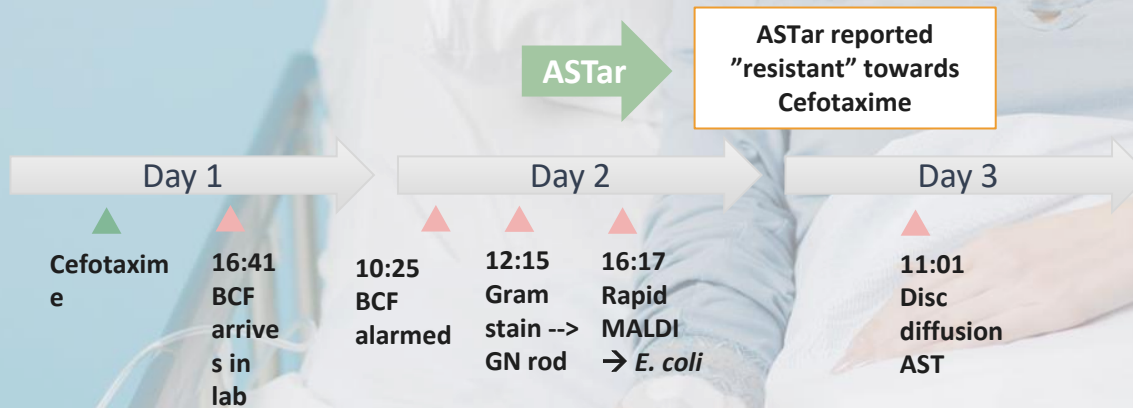
Time to Actionable results is what matters for septic patients

Rapid AST could help saving lives

One example for Uppsala University Hospital pre-clinical study

ASTar was much faster than standard AST method and provided a broader answer

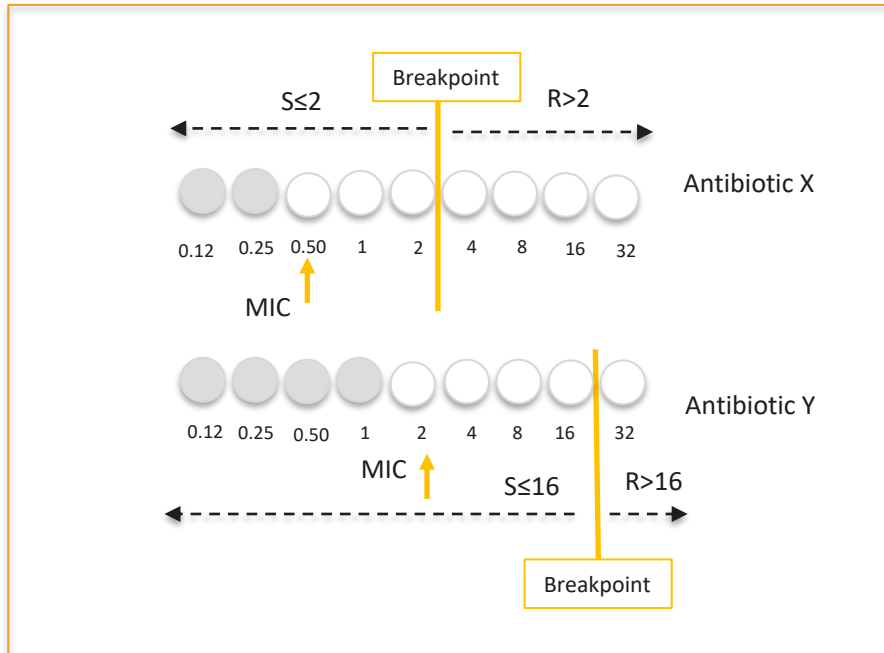
Man 73 years from neuro surgery intermediate care ward, diagnosed with aspiration pneumonia



ASTar performed analysis of **10 additional antimicrobials** compared to standard AST and could report the result up to one day faster

True MIC matters:

The MIC drives the choice of the optimal antimicrobial amongst those the pathogen is susceptible to



The further the MIC from its *breakpoint*, the lower the risk of developing resistance.

The antibiotic X has a MIC of 0.5 mg/L and breakpoint 2 mg/L, and the antibiotic Y has a MIC of 2 mg/L but breakpoint 16 mg/L: the drug with a more favorable MIC is the antibiotic Y.

Therefore technologies that provide SIR-only cannot fully inform optimal antibiotic therapy decisions, as the MIC is needed to choose the most effective antibiotic.

True MIC matters:

MIC value can guide treatment for better patient outcome

Despite Staphylococcus Aureus is called susceptible to vancomycin for MIC values ≤ 2 (EUCAST), in clinical practice vancomycin is not used if MIC=2 because the risk of toxicity would increase significantly at the dosage required to elicit therapeutic effects.

The PK/PD target of Vancomycin to treat a MRSA infection is AUC_{0-24} / MIC of 400.

Roberts et al. Lancet Infect Dis 2014 June 14(6):498-509

MRSA strain x

Vancomycin MIC=0.5 mg/L (S)

- AUC_{0-24} of 200 mg.h/L is required
- Achievable comfortably with a trough concentration exceeding 10 mg/L

MRSA strain Y

Vancomycin MIC=2 mg/L (S)

- AUC_{0-24} of 800 mg.h/L is required
- Necessitating a target trough concentration > 20-25 mg/L which would **dramatically increase the risk of drug related toxicity**

In this case a SIR-only would not allow to avoid antibiotic overexposure and toxicity

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 **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.

Key highlights second quarter

A very strong and important quarter

ASTar receives CE-IVD for first product in May – Gram negative bacteria in BSI

- Excellent data

- Broad coverage

- Strong usability feedback

US clinical study for ASTar started in June

- Q-linea will perform a major part of the study in-house

- Reputable US hospitals in late stage contracting phase

- Thermo Fisher Scientific preparing to start reference testing

First step in commercial launch strategy started




- Several sites currently participating in commercial evaluation of ASTar

- Q-linea's plan does not involve achieving positive margins for the first year of the launch

- Strategic placements and an initial low volume on kits vs. instruments

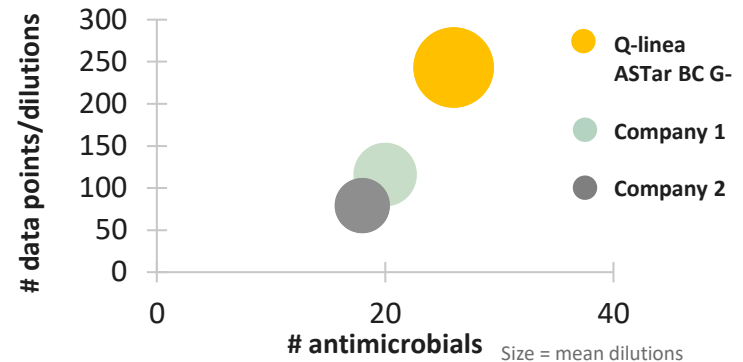
Key highlights second quarter – ASTar CE-IVD May 4th

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 ASTar® Instrument and ASTar® 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

Key highlights second quarter

Successful directed share issue

- Gross proceeds of 301 million SEK
- Enable strengthening commercial activities
- Faster production capacity ramp-up activities
- Support product and geographical expansion

Successful development of the portable culturing technology

- Fully autonomous prototypes tested with excellent results
- European and US market study ongoing

- Could enable more streamlined workflow in the lab
- Can save >10 hours for blood culture results
- Could provide equal and better care for everyone

Use time instead of waste time



Q-LINEA 

The effects of the Corona pandemic on Q-linea

A slow but steady move back to a more normal life...

Q-linea has seen a decrease in Covid cases within the company and more employees have now been vaccinated.

We have for the first time since the pandemic started been able to de-escalate some protective measures.

So-far no major changes in timelines du to Corona/Covid-19.

Future possible effects of the Corona pandemic

The timeframe of the planned US clinical study can still be affected, where, for example the hospitals are tied up with activities related testing of Coronavirus and covid-19.

The situation may also affect the commercial activities in the launch phase for both Q-linea and the partner Thermo Fisher Scientific.

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

We will follow the development carefully and although we see appositive development it is not over yet.

Income statement second quarter

Net sales in the second quarter amounted to SEK 4.3 million (0.1).

Cost of Goods Sold and production costs SEK -9.3 (0) million

includes a write off of total SEK -2,8 million

Gross margin SEK -5,0 (0) million ; -117 (0) %

Operating result totalled SEK -68.2 million (-58.6).

The company reported a loss after tax of SEK -67.9 million (-57.4).

Earnings per share, before and after dilution amounted to SEK -2.47 (-2.37).

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.

Balance sheet at the end of Q2

Cash and cash equivalents amounted to SEK 48.1 million (10.1)

Short-term investments in fixed-income funds SEK 221,4 million (165,7) and the current portion of non-current assets (listed bonds) SEK 57.1 million (131.0).

Non-current assets, listed bonds SEK 184.2 million (24.4).

Inventories amounted SEK 22.6 million (12.4).

includes a write off of total SEK -2,8 million

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.

Cash flow statement second quarter

Cash flow from operating activities SEK -45.0 million (-54.8).

Decrease in cash outflow from operating activities mainly due to an improvement in changes of the working capital that exceeded the larger operating result compared to the same quarter last year.

Cash flow from investing activities SEK -203.3 million (-190.3).

Investment of surplus liquidity from the direct issue in June in Short-term interest funds and Listed bonds.

Cash flow from financing activities SEK 284 million (254.7).

The company carried out direct issue of SEK 301.4 million (270) less issue cost of SEK -17.3 million (-15.2)

Cash and cash equivalents, Short term investments and listed bonds at the end of second quarter amounted **SEK 510.8 million** (331.3). The Board's assessment is that the existing working capital, as of 30 June 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