Company presentation

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Q-linea in brief

Introduction to the company

Headquarters, Marketing and demo lab, Consumable production in Uppsala







Developing innovative and disruptive solutions for faster infectious disease diagnostics, first product targeting sepsis

Global partnership with Thermo Fisher Scientific for commercialization of ASTar

Production of instruments and consumables in Sweden

140 employees & consultants

Pre-market activities has started

European clinical study for ASTar in final stage Indicative results very positive

Received first order on ASTar, value SEK >8 m

First site for US clinical study signed

Lead product ASTar®





Why is improved infectious disease diagnostics important?

Sepsis

AMR

Antimicrobial Resistance

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⁾

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 5)

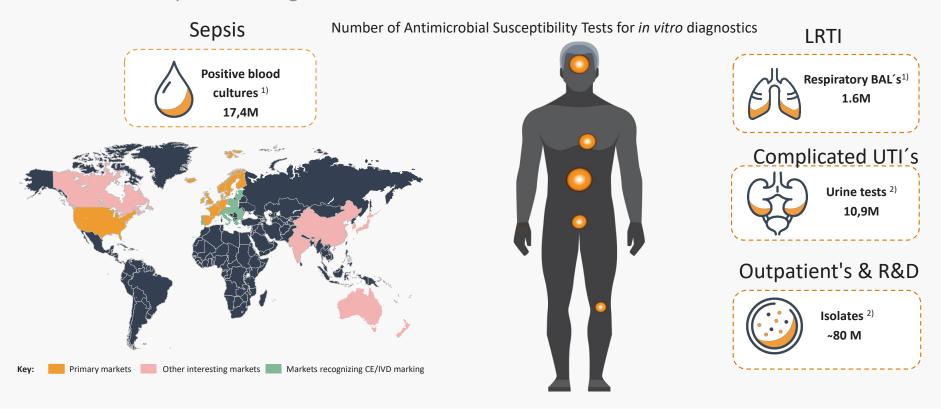
Deaths due to AMR⁵⁾

In 2016, ~700 00 died
In 2050, 10 000 000 are expected to die



Large addressable market for rapid AST diagnostics instruments

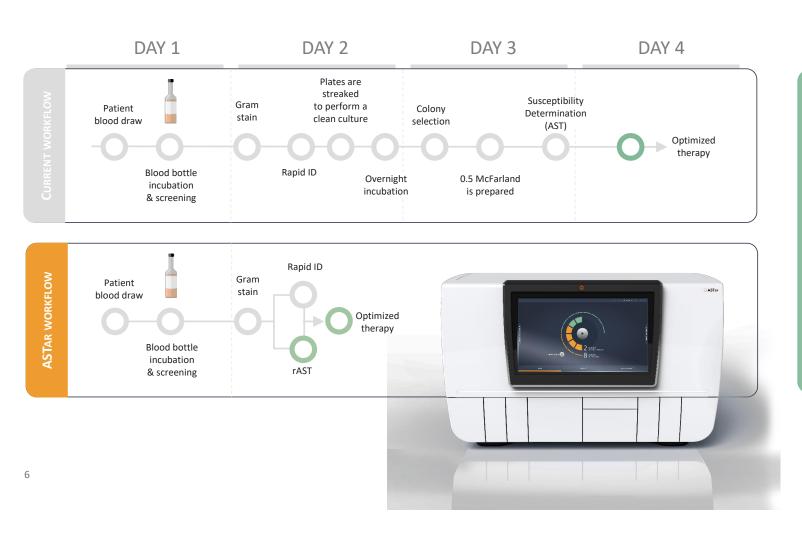
ASTar has several potential target markets



- 1) Blood from positive blood culture. Source: Management account on estimated annual addressable market volume, US + CE + APAC,
- 2) Management account on estimated annual addressable market volume, US + CE



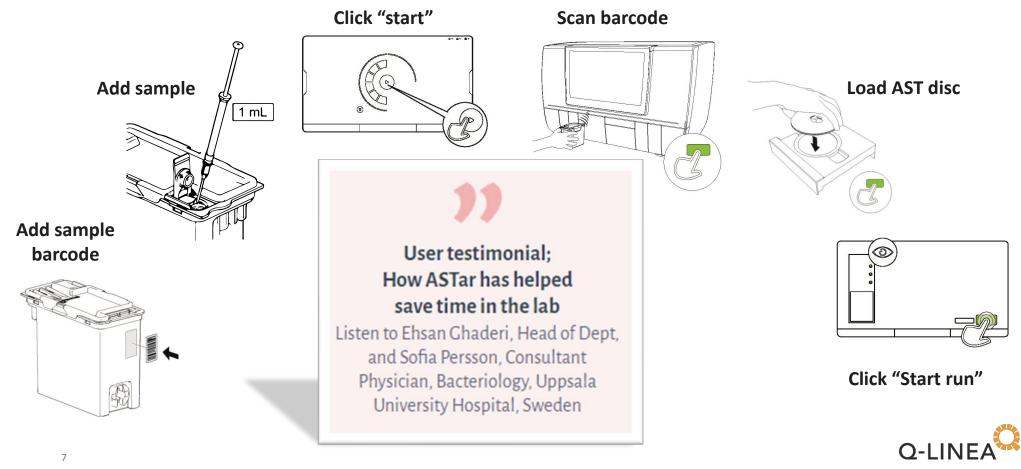
Up to 40 hours faster actionable results with less resources



Time to
Actionable
results is
what
matters for
septic
patients



ASTar enables anyone at the lab to load sample anytime



Health economic benefits of faster 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

 $^{\sim}$ \$2,500 – \$20,000 cost savings per patient³⁾



ASTar can provide 24-40 hour faster diagnostics

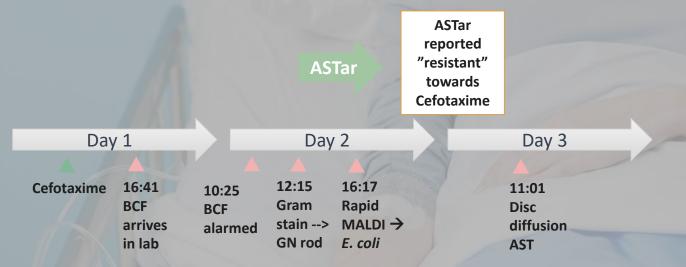
Source: 1) Patel et al, J Clin Microbiol. 2017 Jan; 55(1): 60–67., ECCMID 2017, poster OS1033, Andreassen et al. Cost-effectiveness of MALDI-TOF and rapid antimicrobial susceptibility testing for high-risk patients, Huang et al. Clin Infect Dis. 2013 Nov; 57(9): 1237-45. 2) Fridkin et al, MMWR, 2014;63(9),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

Rapid AST will save 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**



The AST market, ASTar is designed to handle any sample & workflow

Rapid AST

Semi-automated workflow User is required to perform sample preparation

Semi-automated workflowUser is required to perform sample preparation

Traditional isolate AST

High volume











Less than 1 minutes hands-on time

Fully-automated workflow







24/7 capability, all labs & staff



Source: Public material, company presentations, Note: providing solutions on the market or in development



ASTar- designed to save lifetimes

Developed together with our future **customers**

Easy to use

- Fully automated
- <1 min hands-on time</p>
- Load-and go workflow

Fast

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



Comprehensive

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

Accurate

- True MIC results
- High reproducibility



Excellent and accurate data from over 5,900 bug-drug combinations

Technology proven on positive blood culture bottles

FDA and ISO requirements ^{1,2)}		
Essential agreement = Same as reference		
FDA	ISO	Q-LINEA
89.9%	90%	97.5 %³
Categorical agreement = Correct treatment recommendation		
FDA	ISO	Q-LINEA ^Q
89.9%	90%	94.7%³

- Extensively tested on clinically relevant pathogens in correct sample matrix
 - Over 380 different strains including several challenge strains
 - ✓ 25 different species
 - ✓ Gram positive and Gram negative bacteria
 - ✓ Fastidious pathogens
- 30 different antibiotics
- In total over 5,900 bug-drug combinations to date steadily increasing.

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 data from the first 526 bug/drug combinations on positive BACTEC™ Plus Aerobic/F blood culturing bottles



Preparation towards launch together with Thermo Fisher Scientific



Partnership at full speed ahead

 We share the view on how to improve and what is needed to change future infectious disease diagnostics

Key aspects of partnership agreement

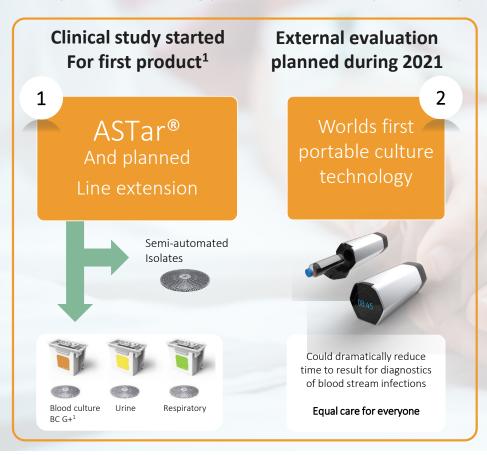
- World-wide exclusivity for ASTar, apart from Sweden
- Share customer data and full insight in sales
- Mutual exclusivity for rapid AST

Ongoing activities

- Pre-market activities ongoing at full speed
- Training of personnel ongoing
- Discussion further collaborations



Unique technology enables disruptive expansion opportunities







Source Company data

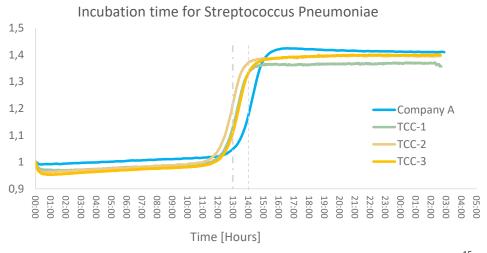


Disruptive technology for blood culture

Has potential to provide equal end better care for all patients

- Could save >10 hours for blood culture results
- Could enable more streamlined workflow in the lab
- Use time instead of waste time

Faster results compared to current best-in-class culture cabinet





Blood culture is central in sepsis diagnosis

Blood culturing market for Eu and US exceeds 1,5 Bn USD

