



Q-LINEA

Company presentation

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Jonas Jarvius, PhD, CEO & President
Co-founder



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Q-linea in brief

Headquarters, Marketing and demo lab, Consumable production in Uppsala



Introduction to the company

- Q-linea is developing disruptive solutions for faster infectious disease diagnostics
- Q-linea entered global partnership with Thermo Fisher Scientific for commercialization of ASTar®
- First product is ASTar with a initial focus on blood stream infections and particularly sepsis
- Production of instruments and consumables in Sweden
- 106 employees & consultants end of 2019
- Opened the marketing & demo lab in February
- Goal is to present ASTar at ECCMID 2020
“now in a virtual form”

Lead product ASTar



Selected 3 years in a row as one of Sweden's most promising & innovative companies



Combating our times most urgent healthcare problem - sepsis



Sepsis is the **leading cause of death** in U.S. hospitals¹⁾, killing **>500,000 people** yearly in the EU and US²⁾

Sepsis is also the **#1 hospitalization cost in the US** with over \$24bn yearly³⁾

Mortality increases 7.6% for **every hour** of delayed treatment⁴⁾

Up to **200,000 of these deaths** could be **prevented with** 24 hours **faster diagnosis**⁵⁾

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) Kumar et al, Crit Care Med. 2006 Jun;34(6):1589-96 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.

Q-linea provides rapid actionable results in sepsis diagnosis

Identification analysis (ID) – “What bug”

- To determine identity of the causative pathogen e.g. *E. coli* bacteria
- And if applicable determine the presence of resistance genes e.g. *MecA* (expressed by many MRSA bacteria)

Antibiotic susceptibility test analysis (AST) – “What drug”

- To determine what antibiotic drug that is effective against the identified pathogen
- And what minimum inhibitory concentration (MIC) that inhibits growth (or kills) the identified pathogen

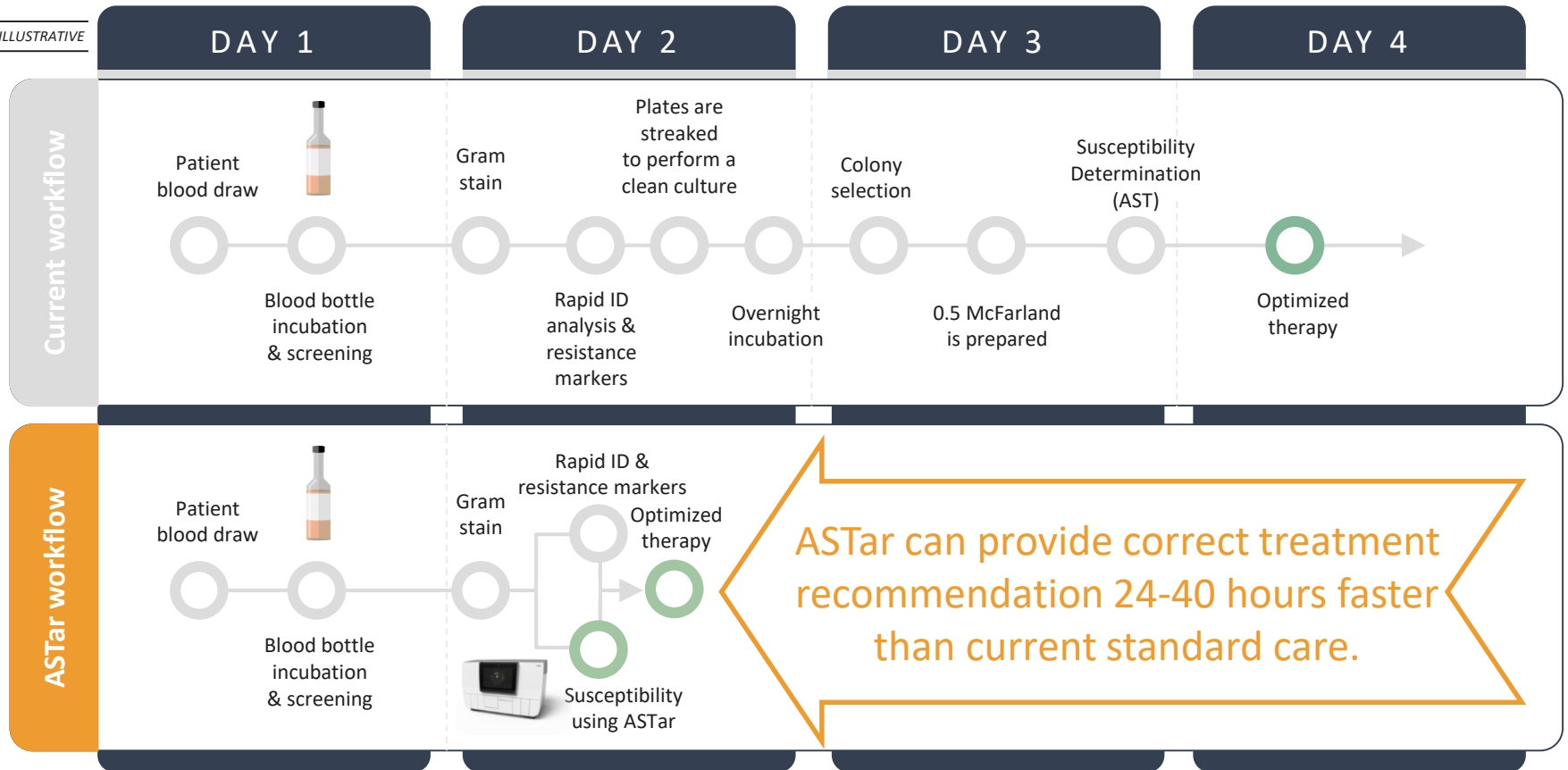
Considered most important information for sepsis treatment

ASTar



More than 24 hours faster actionable results with ASTar

ILLUSTRATIVE



Note: Workflow analysis performed by Q-linea at several European and US hospitals. Workflow may differ between laboratories.

Health economic benefits of 24h faster AST on septic patients

Rapid and efficient solution results in significant health economic benefits

Lower mortality

Up to 40%
lower mortality rates²⁾

Less pressure for resistance and superinfections

Up to 25%³⁾
reduction of *C. difficile*
infections caused by broad-
spectrum antibiotic
treatment

Decreased length of stay and reduced severity

~\$2,500 – \$20,000
in cost savings per patient¹⁾

Source: 1) 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. 2) 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. 3) Fridkin et al, MMWR, 2014;63(9), 194-200

Q-linea's lead product candidate ASTar – a modular AST system

Rapid

- Phenotypic AST results in 3 to 6 hours for blood
- Answer <45 minutes for e.g. urine

Simple to use

- Fully automated
- Up to 12 samples analysed in parallel
- Up to 50 samples per day

Comprehensive

- Many samples: positive blood culture flasks, clinical samples or isolates
- Up to 48 antibiotics in 5-11 two-fold dilutions

ASTar offering

System



Consumables

Fully-automated High-value test



Blood, cUTI, LRTI



Semi-automated Isolate test



Isolates, UTI

Excellent and accurate data from over 3700 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 
89.9%	90%	94.7% ³

- Extensively tested on clinically relevant pathogens in correct sample matrix
 - ✓ Over 270 different strains including several challenge strains
 - ✓ 25 different species
 - ✓ Gram positive and Gram negative bacteria
 - ✓ Fastidious pathogens
- 30 different antibiotics
- In total over 3700 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. Company data from the first 526 bug/drug combinations on positive BACTEC™ Plus Aerobic/F blood culturing bottles

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

Rapid AST

Traditional isolate AST

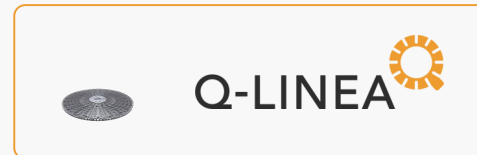
Fully-automated workflow
Less than 1 minutes hands-on time

Semi-automated workflow
User is required to perform sample preparation

Semi-automated workflow
User is required to perform sample preparation

High value

High volume



24/7 capability, all labs & staff



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

Large addressable market for rapid AST diagnostics instruments

AS^{Tar}® has several potential target markets

Number of Antimicrobial Susceptibility Tests for *in vitro* diagnostics

Sepsis



Positive blood cultures¹⁾
17,4M

LRTI



Respiratory BAL's¹⁾
1.6M

Complicated UTI's

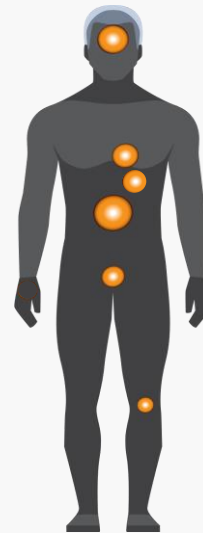
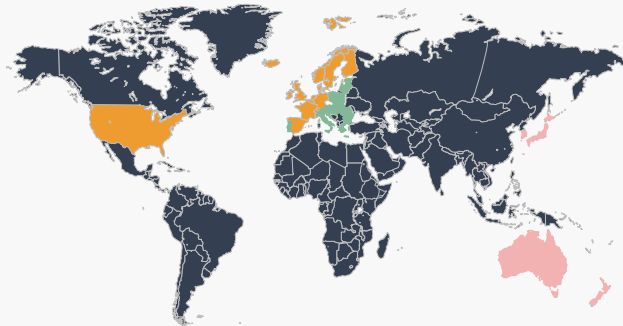


Urine tests²⁾
10,9M

Outpatient's & R&D



Isolates²⁾
~80 M

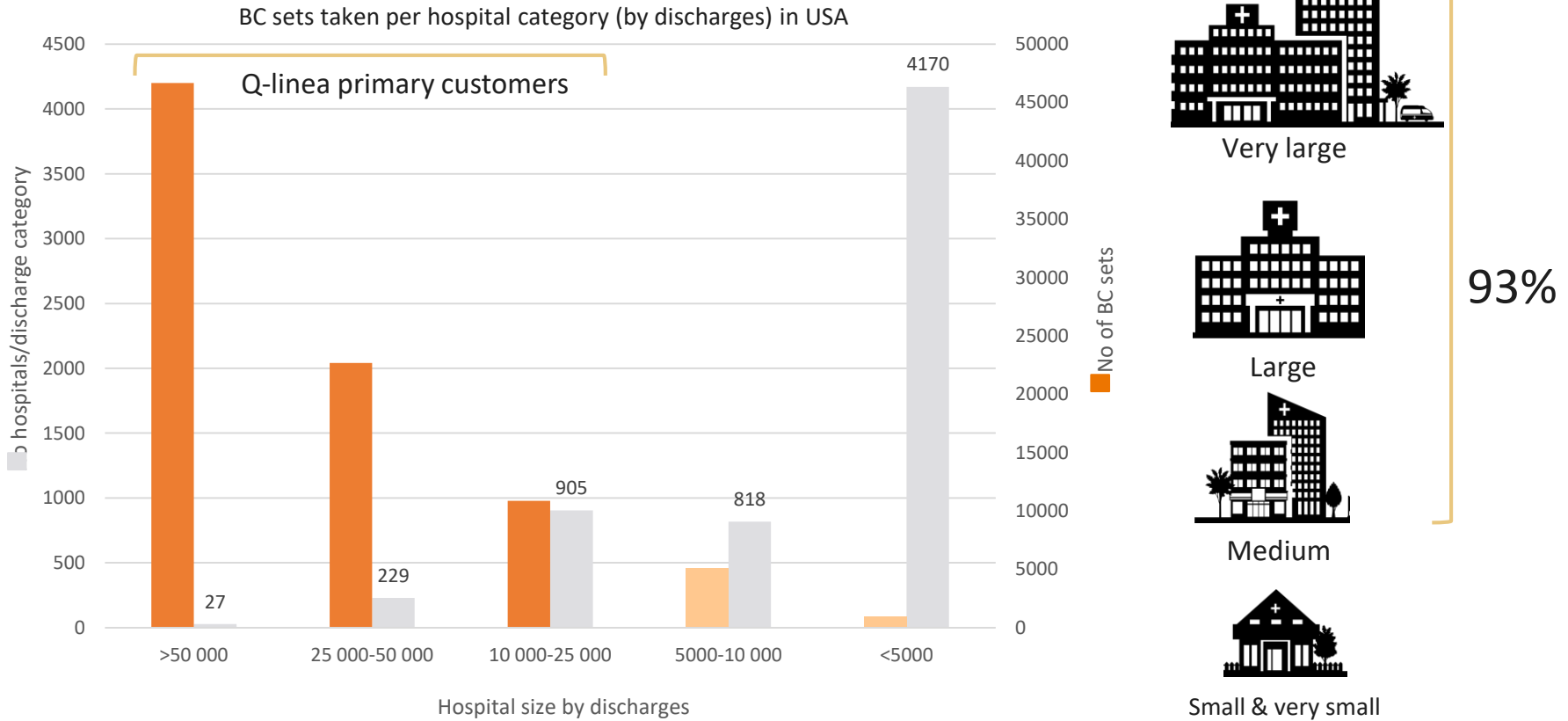


Key: ■ Primary markets ■ Other interesting markets ■ Markets recognizing CE/IVD marking

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

A few large hospitals accounts for the majority of blood cultures



Source: "Clinical Values 2018 and Company Internal data"

ASStar key highlights & value proposition

Disruptive AST analysis

- 1 Broad panel coverage → Enables both **escalation & de-escalation**
Minimize need for follow-up tests required
- 2 Broad pathogen coverage → Includes both **fastidious & non-fastidious** bacteria
- 3 High throughput & Random access → **Up to 50 patient** samples / 24h
- 4 Complete solution → One system can run both:
High-value tests & isolates at competitive pricing



Source: Company websites, Poster presentations, product samples etc. *When comparing same number of antibiotics analyzed

Go-to-market strategy with strategic sales partner



Common vision

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

Gain market access quickly

- Global and local reach
- Strong customer relationships
- Access to large organizations immediately

Legitimacy

- Strong brand & world wide presence
- Proven track-record of selling high-quality products to target customers

Logistics

- Efficient logistics setup

Sales and service

- First line service
- Second line customer support

Key aspects of partnership

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

Key activities for upcoming launch of AS*T*ar

Achievements

2019

US study design approved by the FDA

AS*T*ar passes EMC (ElectroMagnetic Compatibility) testing

More than 3700 bug-drug combinations tested

2020

Global sales partnership with Thermo Fisher for AS*T*ar

Future key events

Opening of new consumable production facility in Uppsala

Market presentation of AS*T*ar at ECCMID, Paris

Start of clinical trials during second half of the year

Source: Company information.