Q-LINEA

Company presentation
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Q-linea in brief

Headquarters, Marketing and demo lab, Consumable production in Uppsala

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

Entered global partnership with Thermo Fisher Scientific for commercialization of ASTar®

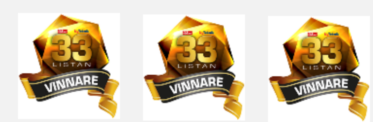
Production of instruments and consumables in Sweden

122 employees & consultants

Moving closer to start clinical studies for ASTar

Lead product ASTar®

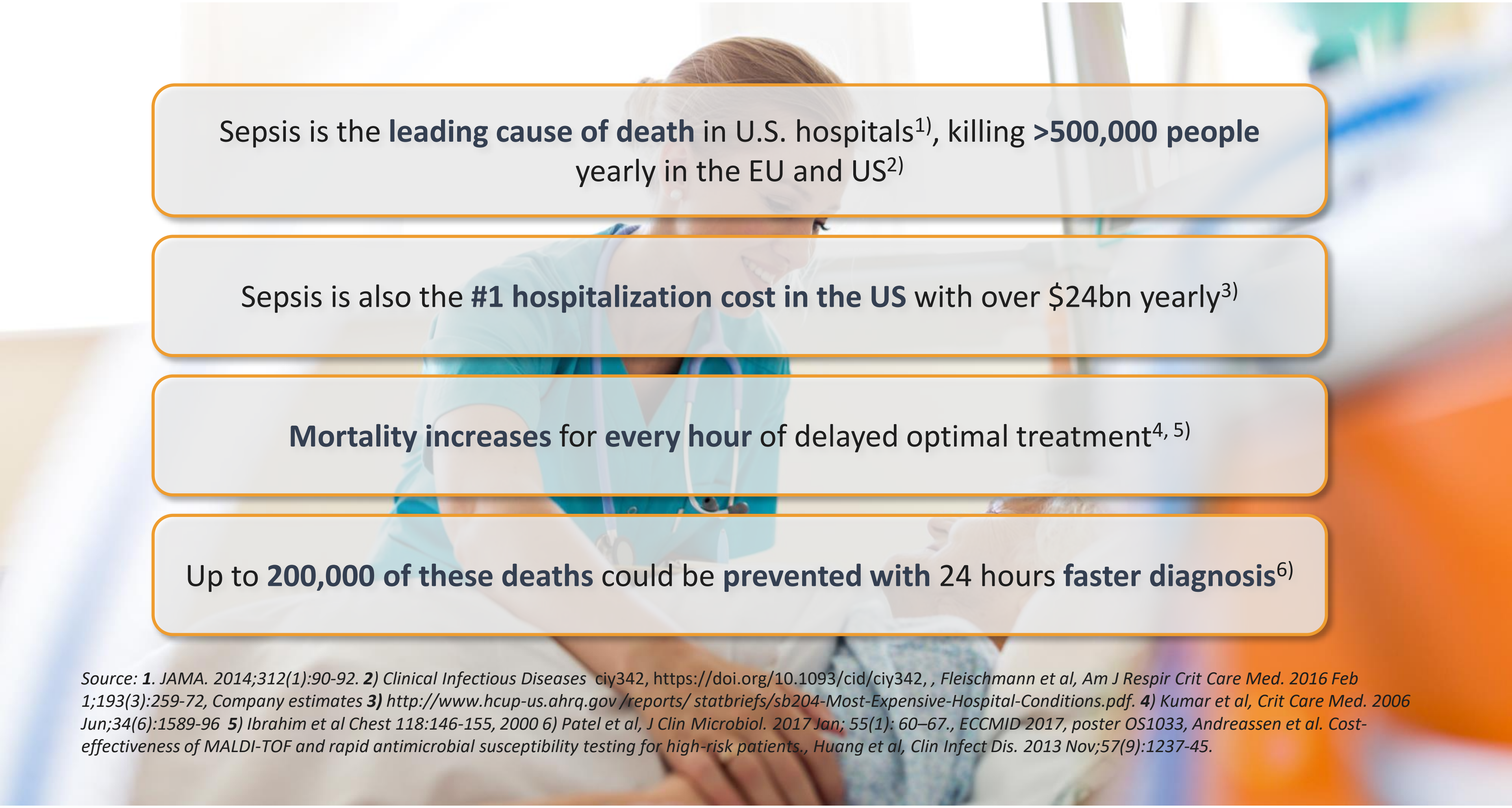
Selected 3 years in a row as one of Sweden's most promising companies



Source: Company information

Q-LINEA

Combating an urgent healthcare problem - sepsis



Sepsis is the **leading cause of death** in U.S. hospitals[1)], killing **>500,000 people** yearly in the EU and US[2)]

Sepsis is also the **#1 hospitalization cost in the US** with over $24bn yearly[3)]

Mortality increases for **every hour** of delayed optimal treatment[4, 5)]

Up to **200,000 of these deaths** could be **prevented with** 24 hours **faster diagnosis**[6)]

*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**) Ibrahim et al Chest 118:146-155, 2000 6) 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

Antibiotic susceptibility test analysis (AST) – "What drug"

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

ASTar

Considered most important information for sepsis treatment

Q-LINEA

ASTar is designed to improve clinical outcomes

Fast

- Phenotypic AST results in 3 to 6 hours
- Enables quick escalation, de-escalation and dosage adjustments
- Less than 1 min hands-on time

Simple to use

- Fully automated
- Up to 12 samples analysed in parallel
- Up to 50 samples per 24 hours

Accurate & broad answer

- True MIC results
- Up to 48 antibiotics possible
- 6-14 two-fold dilutions of each antimicrobial in panel

ASTar offering

System

Consumables

Blood, cUTI*, LRTI**

Isolates, UTI*

*(c)UTI = (Complicated) Urinary Tract Infection
**LRTI = Lower Respiratory Tract Infection

Q-LINEA

Accurate and reproducible data from over 4000 bug-drug combinations

Technology proven on positive blood culture bottles

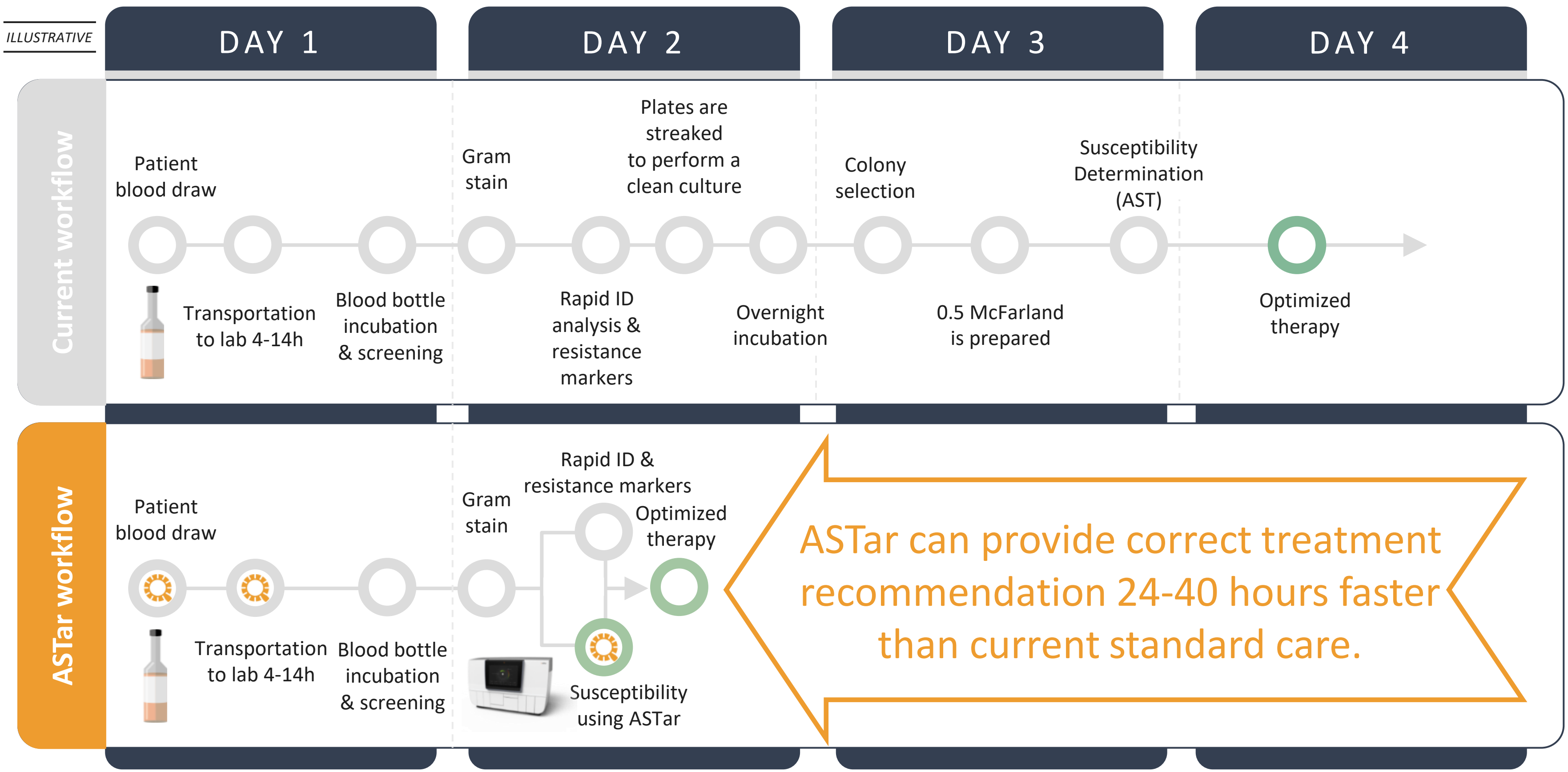
FDA and ISO requirements[1,2)]		
Essential agreement = Same as reference		
FDA	**ISO**	Q-LINEA
89.9%	90%	**97.5%[3]**
Categorical agreement = Correct treatment recommendation		
FDA	**ISO**	Q-LINEA
89.9%	90%	**94.7%[3]**

- 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 4000 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

Q-LINEA

More than 24 hours faster actionable results with ASTar



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 rates[2]

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 patient[1]

*Source: **1**) 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 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*

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**
Q-LINEA	Q-LINEA	Q-LINEA
Accelerate Diagnostics QuantaMatrix	Aperture Bio Astrego Diagnostics Alifax BacterioScan – Answers Before Antibiotics First Light Diagnostics FASTinov – Next Generation Antimicrobial Assays GeneFluidics Gradientech Pocared Diagnostics LifeScale Selux Dx Spectral Platforms Inc. – Rapid Diagnosis. Saving Lives. Saving Costs. Symcel Specific	Thermo Fisher Scientific BD bioMérieux Industry Beckman Coulter
24/7 capability, all labs & staff		

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

ASTar provides a comprehensive, easy-to-use and rapid solution

Disruptive AST analysis

1	Broad panel coverage →	Enables both dose **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*

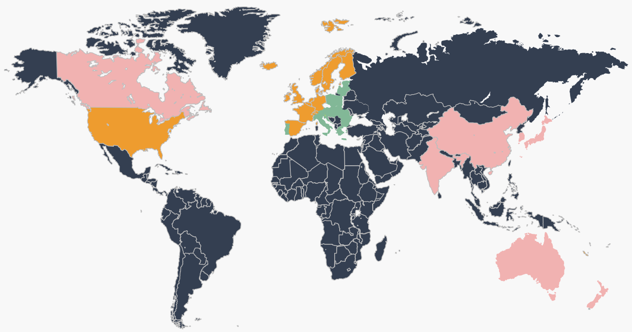
Large addressable market for rapid AST diagnostics instruments

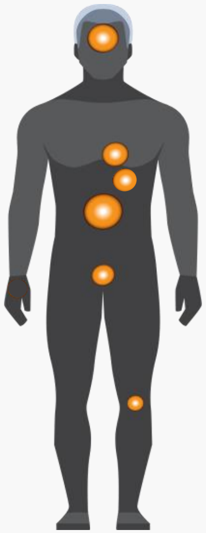
ASTar has several potential target markets

Number of Antimicrobial Susceptibility Tests for *in vitro* diagnostics

Sepsis

Positive blood cultures [1)]
17.4M





Key:
- Primary markets
- Other interesting markets, possible to gain access faster together with Thermo Fischer
- Markets recognizing CE/IVD marking

LRTI

Respiratory BAL´s[1)]
1.6M

Complicated UTI´s

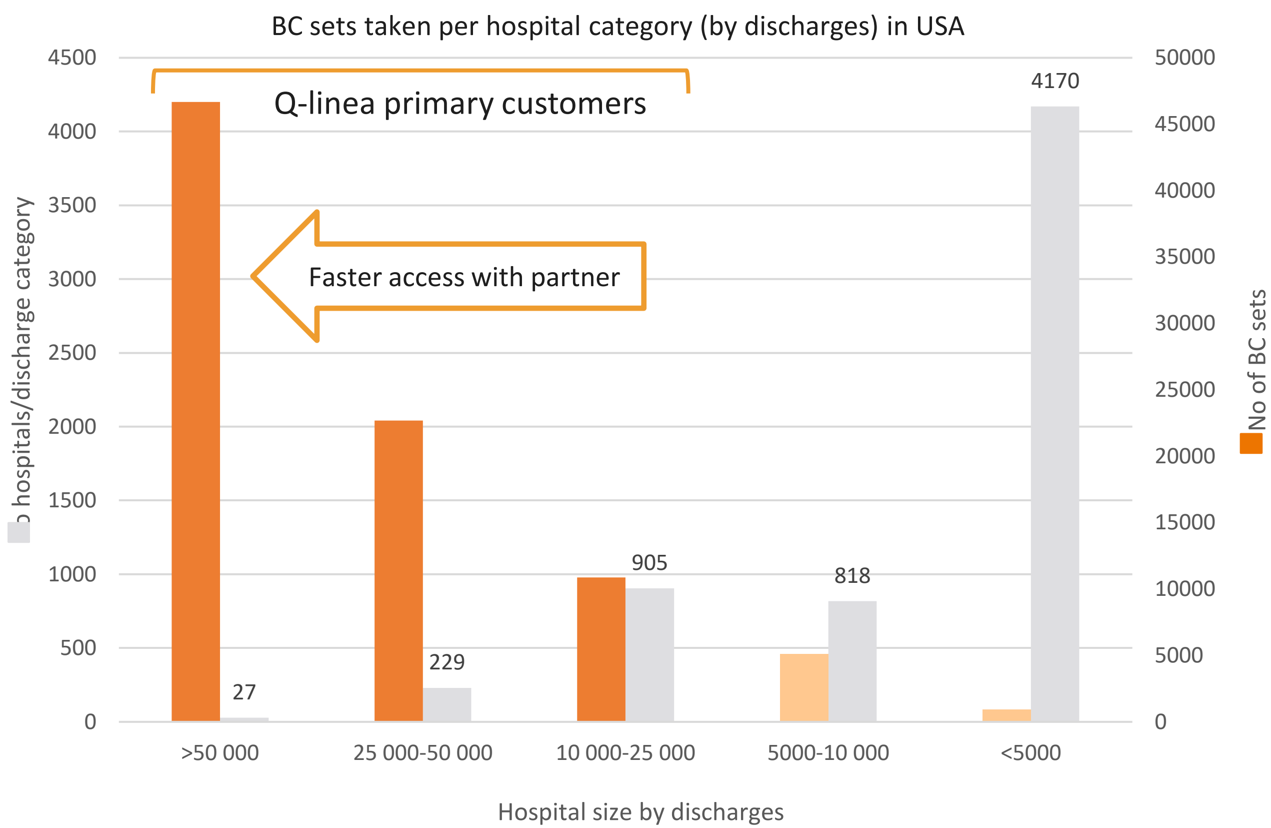
Urine tests [2)]
10.9M

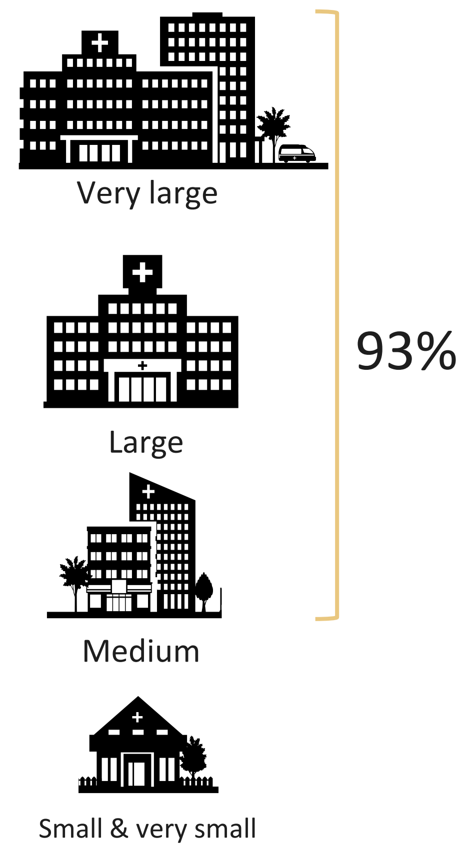
Outpatient's & R&D

Isolates [2)]
~80 M

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

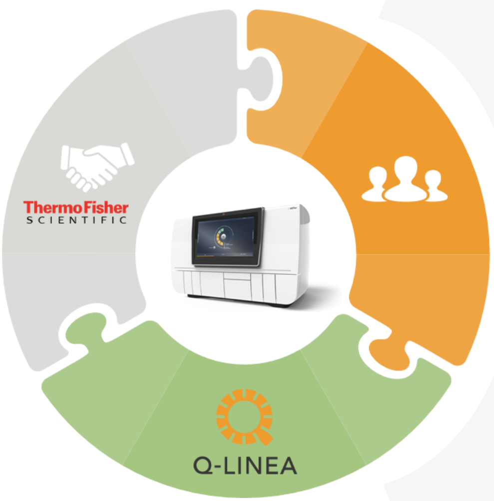
A few large hospitals accounts for the majority of blood cultures





Source: "Clinical Values 2018 and Company Internal data"

Go-to-market together with Thermo Fisher Scientific



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

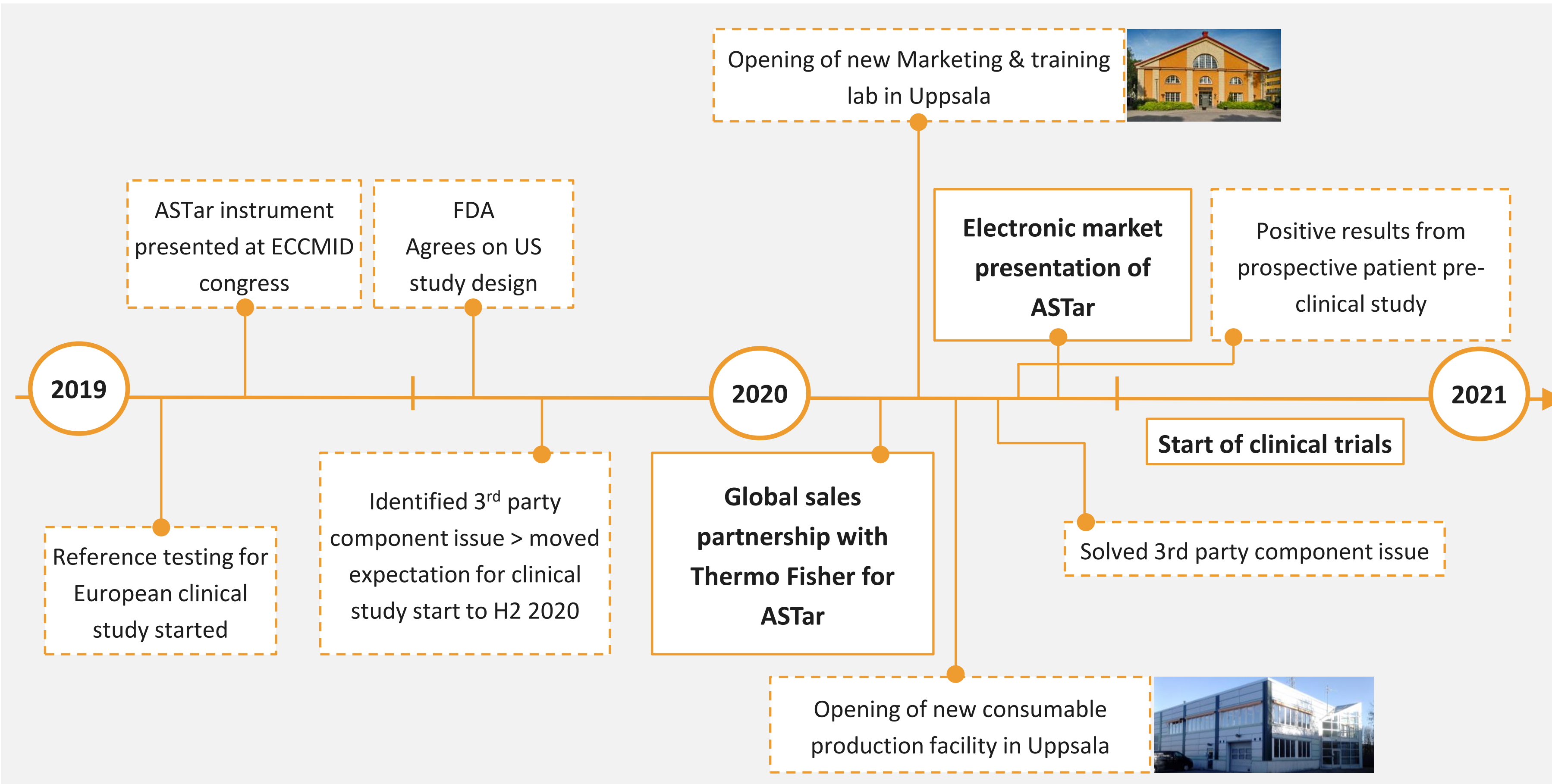
Legitimacy
- Strong brand & world wide presence
- Proven track-record of selling high-quality products to target customers

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 achievements & activities for upcoming launch of ASTar



Key highlights 2020

Unique technology enables disruptive expansion opportunities

1

Line extension for ASTar®

Hospital lab placement

2

Worlds first portable culture cabinet

3

ASTrID®
Direct from patient
ID and AST

4

Ultra rapid urine testing

Point-of-care placement

Semi-automated Isolates

Blood culture BC G+ | Urine | Respiratory

Could dramatically reduce time to result for diagnostics of blood stream infections

Equal care for everyone

Patient data from RISE study
Sensitivity 96%
Specificity 100%

Proof-of-concept data
<45 minute SIR result

Source Company data

Thank you !

&

Q&A


ALERTS
LOGIN
SETTINGS
2 AVAILABLE CARTRIDGE POSITIONS
8 AVAILABLE DISC POSITIONS
RESULTS
QUALITY CONTROL