



Annual General Meeting 2020-05-26  
CEO presentation

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# Q-linea in brief

Headquarters, Marketing and demo lab, Consumable production in Uppsala



- Developing disruptive solutions for faster infection disease diagnostics, first product targeting sepsis
- Entered global partnership with Thermo Fisher Scientific for commercialization of ASTar®
- Production of instruments and consumables in Sweden
- 114 employees & consultants at quarter end
- Goal is to present ASTar electronically on 5<sup>th</sup> of June

Lead product ASTar®



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



Source: Company information.

# 2019 key events & achievements

Sales partner discussion intensifies



ASTar pre-production instrument presented at ECCMID congress



Increased production capacity for consumables

Identified 3<sup>rd</sup> party component issue > moved expectation for clinical study start to h2 2020

2019

2020

Reference testing for European clinical study started

Detailed US study design submitted to the FDA

24/7 testing of ASTar

FDA Agrees on US study design

Access to new production facility



First pre-production ASTar tested in the microlaboratory



10 ASTar under intense evaluation



# Combating an urgent healthcare problem - sepsis

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

Sepsis is also the **#1 hospitalization cost in the US** with over \$24bn yearly<sup>3)</sup>

**Mortality increases for every hour** of delayed optimal treatment<sup>4, 5)</sup>

Up to **200,000** of these deaths could be **prevented with 24 hours faster diagnosis**<sup>6)</sup>

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

**Considered most important information  
for sepsis treatment**

 **ASTar**



# Q-linea lead product ASar – a modular AST system

## Fast

- Phenotypic AST results in 3 to 6 hours
- Answer <45 minutes for e.g. urine
- Less than 1 min hands-on time

## Simple to use

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

## Accurate & broad answer

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

## ASar offering

### System

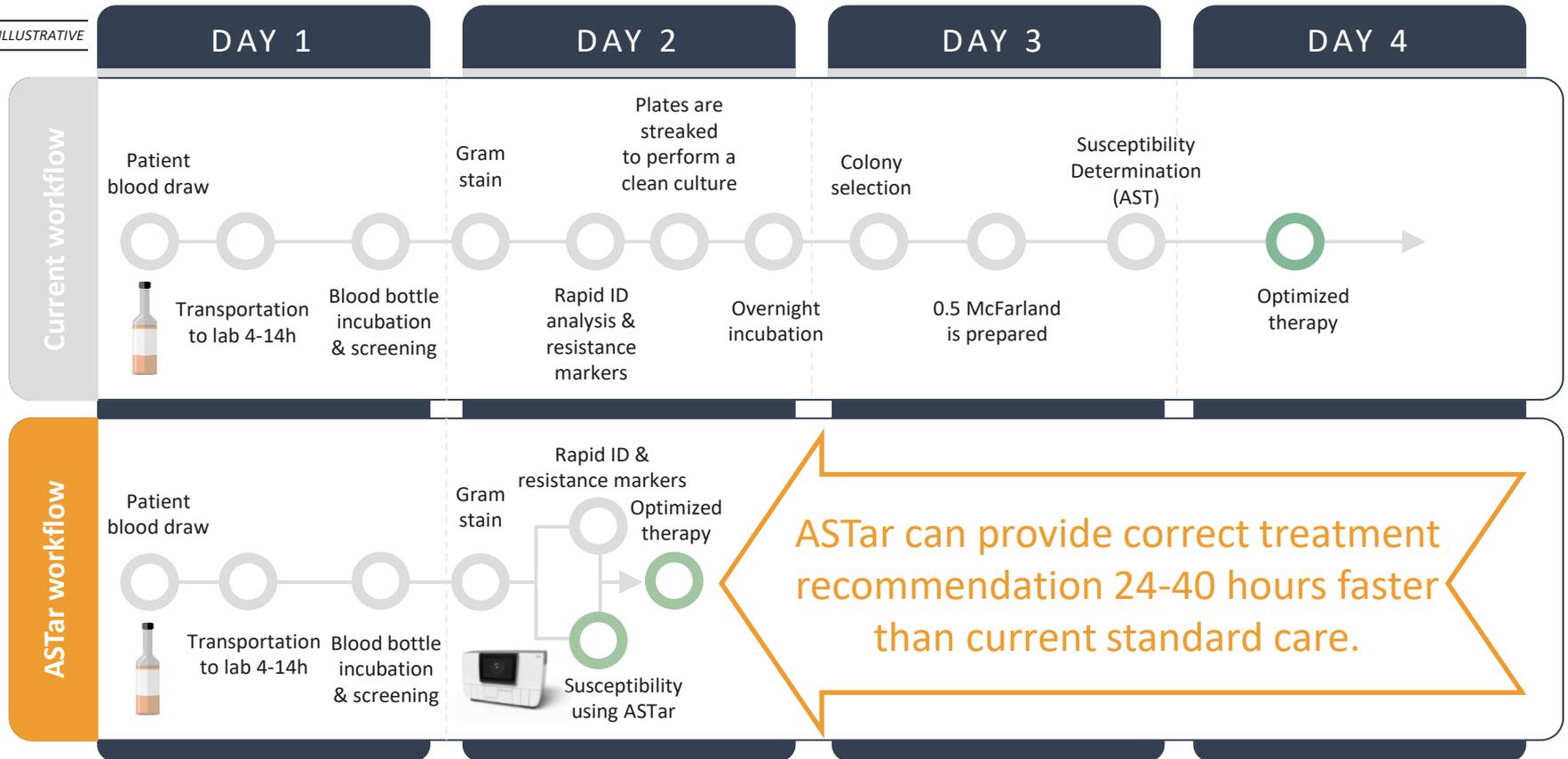


### Consumables



# 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 rates<sup>2)</sup>

## Less pressure for resistance and superinfections

Up to 25%<sup>3)</sup>  
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<sup>1)</sup>

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

# Large addressable market for planned AStar products

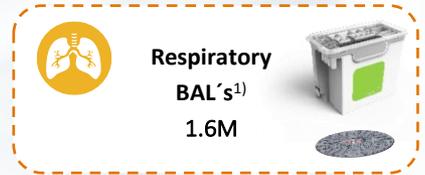
AStar has several potential target markets

Number of Antimicrobial Susceptibility Tests for *in vitro* diagnostics

## Sepsis



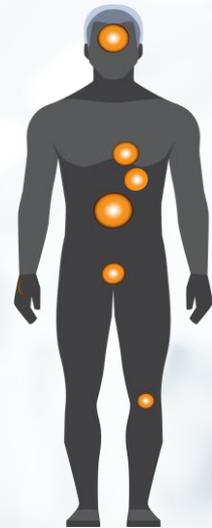
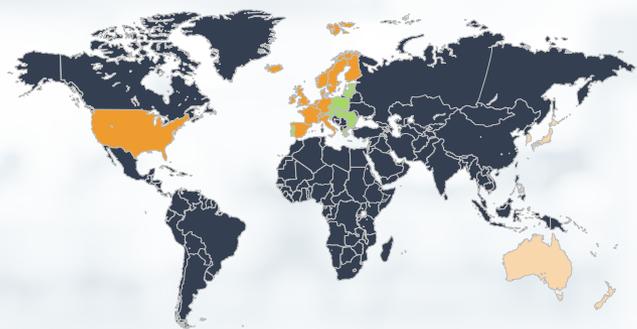
## LRTI "Lower respiratory tract infections"



## Complicated UTI's



## Outpatient's & R&D



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) Source: Management account on estimated annual addressable market volume, US + CE

# A strong partner in preparation for launch

## Q-linea signs global partnership agreement with Thermo Fisher Scientific for the commercialisation of ASTar

- World-wide exclusive for ASTar, except Sweden
- Mutual exclusivity for rapid AST
- Share customer data and full insights in sales process

## We aim to bring the best customer experience

- Unique system & technology, developed together with customers
- Strong brand & world wide presence
- Proven track-record of selling high-quality products to target customers
- Strong customer relationships
- High quality service organisation & expert elevated support

## Fast access to high-volume customers

- Long term relationships with large institutions



# The effects of the Corona pandemic on Q-linea

So far, the effects have not caused a delay on planned clinical study start

We moved all production of consumables from China to Sweden end of last year

Most activities coupled to ASTar launch are still internal

There is a strong interest from our clinical partners to perform studies

Depending on travel restrictions and availability at the sites, the US study may be impacted. We can still perform approximate 1/3 of the US study internally

So far, the adoption of new work routines have had minimal impact on the project during the first quarter. This may change in the upcoming quarters and it also depends on a healthy staff.

We may encounter delayed deliveries of components, since we rely on 3rd parties for various components & possible delays due to restricted access to hospital for clinical studies & sales purposes

*Source: Company information*

# Key activities & achievements for upcoming launch of ASTar

2020

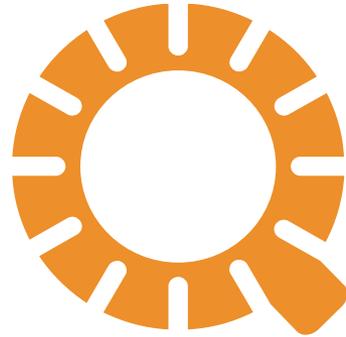
## Achievements

- Global sales partnership with Thermo Fisher for ASTar
- Solved 3<sup>rd</sup> party component issue
- Opening of new consumable production facility in Uppsala
- Positive results from prospective patient pre-clinical study

## Future key events

- Market presentation of ASTar in electronic format on 5<sup>th</sup> of June
- Start of clinical trials during second half of the year

Source: Company information.



**Q-LINEA**