

Company presentation

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Jonas Jarvius, CEO & President

Anders Lundin, CFO



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Q-linea in brief

Introduction to the company

Headquarters, Marketing and demo lab, Consumable production in Uppsala



Developing 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

122 employees & consultants

Pre-market activities has started

Goal is to start the clinical study for ASTar during the 4th quarter

Lead product ASTar



Combating an 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⁾

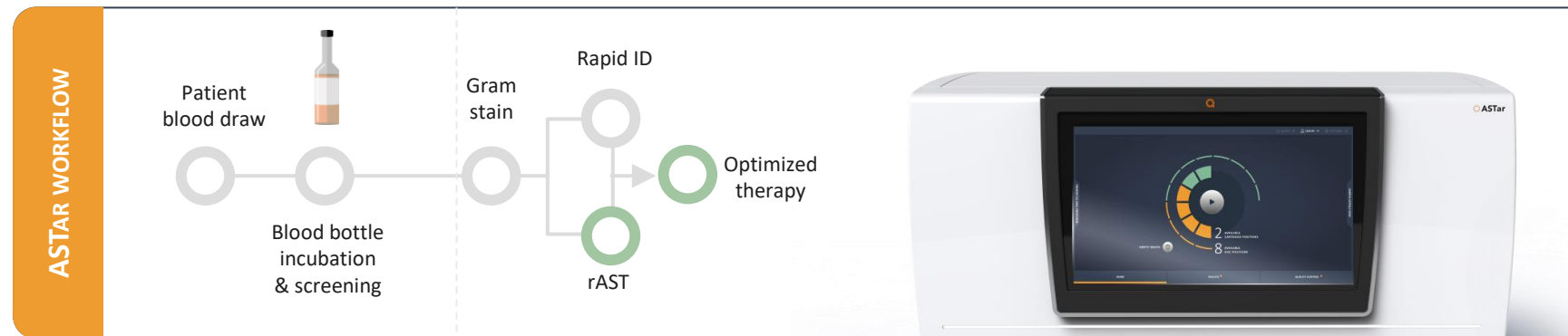
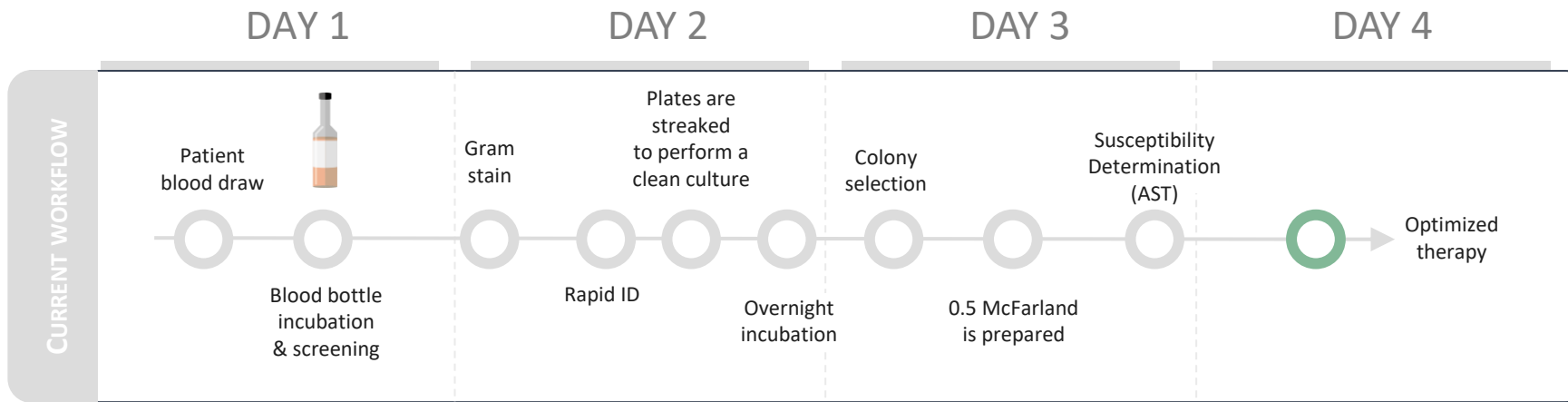
Sepsis is also the #1 hospitalization cost in the US with over \$24bn yearly³⁾

Mortality increases for every hour of delayed optimal treatment^{4, 5)}

Up to 200,000 of these deaths could be prevented with 24 hours faster diagnosis⁶⁾

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.

Up to 40 hours faster actionable results



Time to Actionable results is what matters for septic patients



Health economic benefits of 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⁾

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.

AStar – designed to save lifetimes

Easy to use

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

Fast

- Results in 3 to 6 hours
- High throughput



Comprehensive



- Large antibiotic panel
- Long concentration ranges
- Fastidious and non-fastidious 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 
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. Company data from the first 526 bug/drug combinations on positive BACTEC™ Plus Aerobic/F blood culturing bottles

The AST market, AS*ar 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

AS tar provides a comprehensive, easy-to-use and rapid solution

Broad panel coverage

Enables both dose **escalation & de-escalation**
Minimize need for follow-up tests required

Broad pathogen coverage

Includes both **fastidious & non-fastidious** bacteria

High throughput

Up to 50 patient samples / 24h

Complete solution

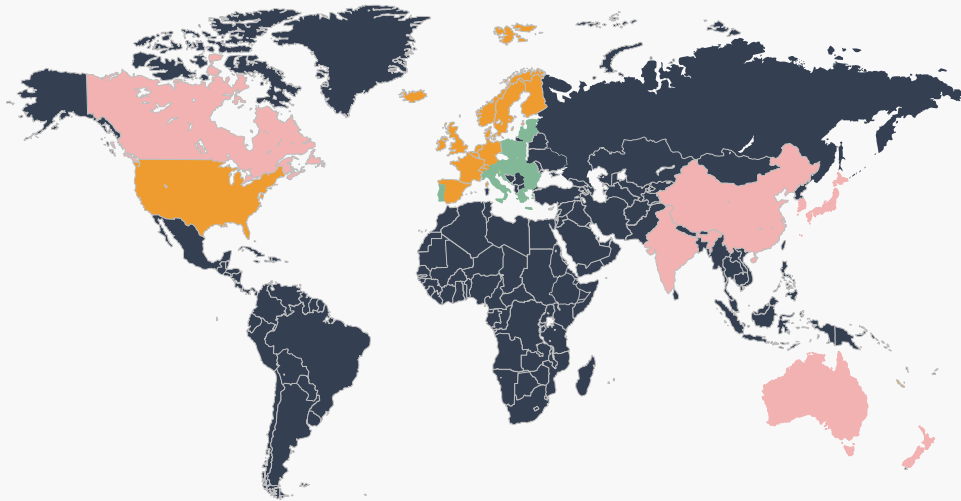
AS tar is designed to handle both: **High-value tests & isolates** at **competitive pricing**

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

Large addressable market for rapid AST diagnostics instruments

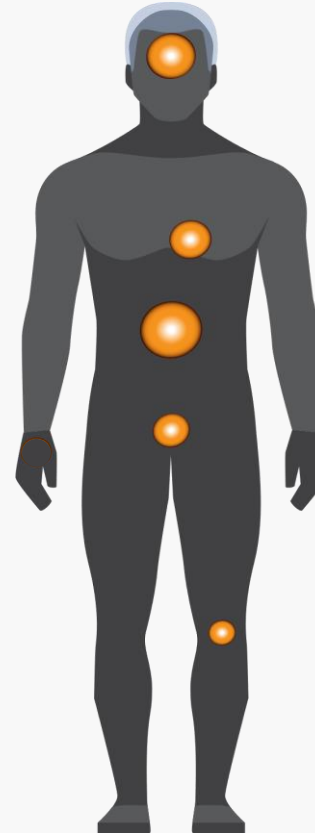
ASTar has several potential target markets

Sepsis



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

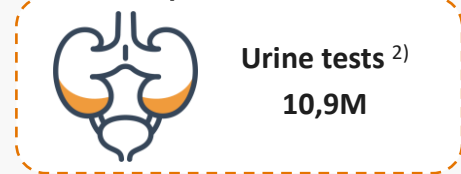
Number of Antimicrobial Susceptibility Tests for *in vitro* diagnostics



LRTI



Complicated UTI's



Outpatient's & R&D



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

Preparation towards launch together with Thermo Fisher Scientific



Partnership at full speed ahead

- High activity in all workstreams
- Logistics & supply chain
- Market message alignment
- Training of personnel
- Discussion further collaborations

Great enthusiasm, spirit and professionalism in both companies



**ASTar is about to
enter clinical studies**