

# FUTURE PROOF HEALTHCARE

A sustainable healthcare for a new generation

## Presentation Q4(23)

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# Q-linea 4th quarter

Q-linea is developing disruptive solutions for faster infectious disease diagnostics, first product targeting sepsis

## Overview

### Key achievements in 2023

- Built a strong distribution partnership network in key geographies in EU
- Started commercially focused subsidiaries in USA and Italy
- Supported several customer ASTar evaluations in EU and US
  - Results are coming in strong, and trigger increased tender activity
- Started Health economic multicentre study in Italy
  - Interim results to be presented at AMCLI 9<sup>th</sup> March 2024

### Important activities after period end

- First tender win in Italy
  - ASTar was technically superior to competing systems
- Extended the Gram-negative panel in EU with MER-VAB
- Final stage of FDA review and clearance of ASTar in US coming closer
- Expecting to submit for NTAP dedicated reimbursement for US market in Q1 – 2024
- Initiated 2<sup>nd</sup> restructuring and cost savings program to reduce development costs and enable focus on commercial activities

## Geographical presence

■ Active markets



## Lead product ASTar<sup>®</sup>



USD FDA  Breakthrough device



## Stuart Gander comes in as new CEO & President



### Stuart Gander

CEO & President from March 1<sup>st</sup> 2024

+17 years' experience in global medtech industry and across diagnostics sector. History of strategic and operational creativity and supporting teams during high-growth and market change

#### Selected experience:



Inspired to make a difference through improved health outcomes and energised by building & leading high-talent teams

Immediate focus: build on the spirit and legacy of Q-linea innovation & engineering prowess while bringing a global and value-oriented mindset to accelerating commercial growth

# Why is improved infectious disease diagnostics important?

## Sepsis

**Rapid diagnostics could reduce mortality with up to 40%<sup>4)</sup>**

~50% of all patients receive inappropriate treatment  
~20% dies before current diagnostic provide results

**Kills >500,000 people yearly in the EU and US<sup>2)</sup>**

Every 3 seconds someone dies of sepsis worldwide

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

Leading cause of death in U.S. hospitals<sup>1)</sup>  
More common than lung, prostate and breast-cancer combined

## Antimicrobial Resistance

**Has been presented as  
“The biggest threat to mankind”**

**Rapid diagnostics would reduce unnecessary prescription**

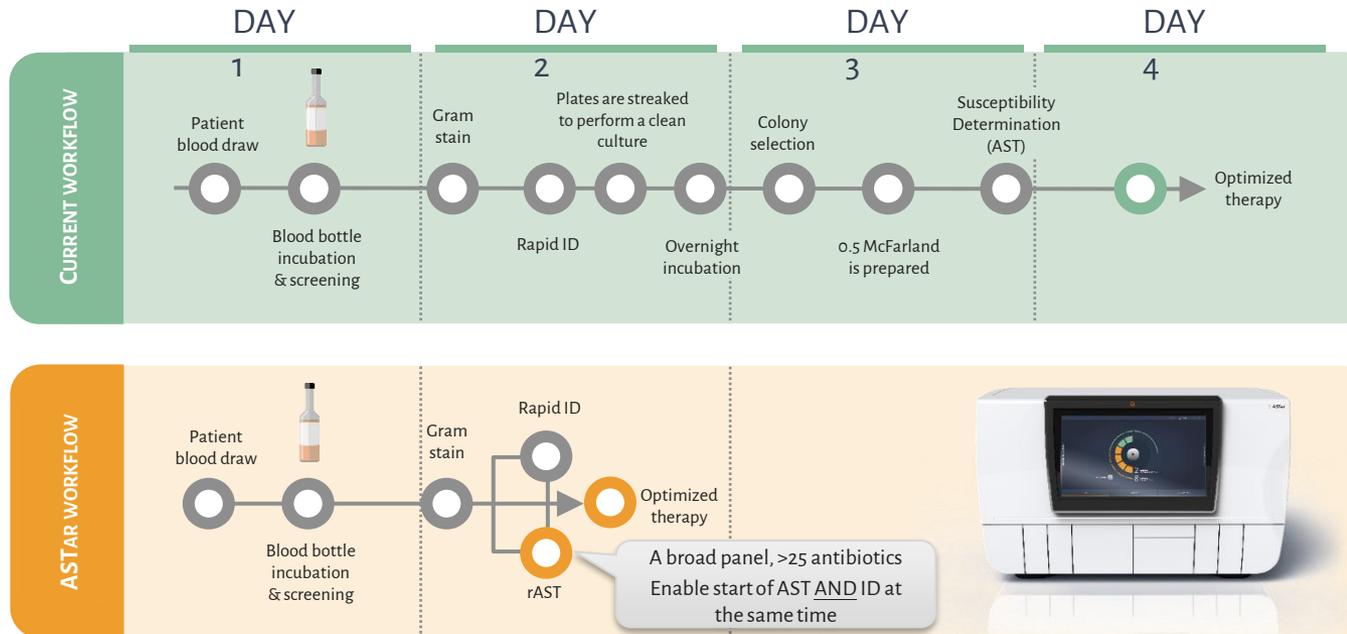
>65 % of all prescribed antibiotics for respiratory issues are unnecessary<sup>5)</sup>

**In 2050, ~10,000,000 are expected to die if we do not act now**

In 2016, ~700,000 people died due to AMR<sup>5)</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. 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. 5. Tackling drug-resistant infections: Final report and recommendations. Review on Antimicrobial Resistance. Web. 2016

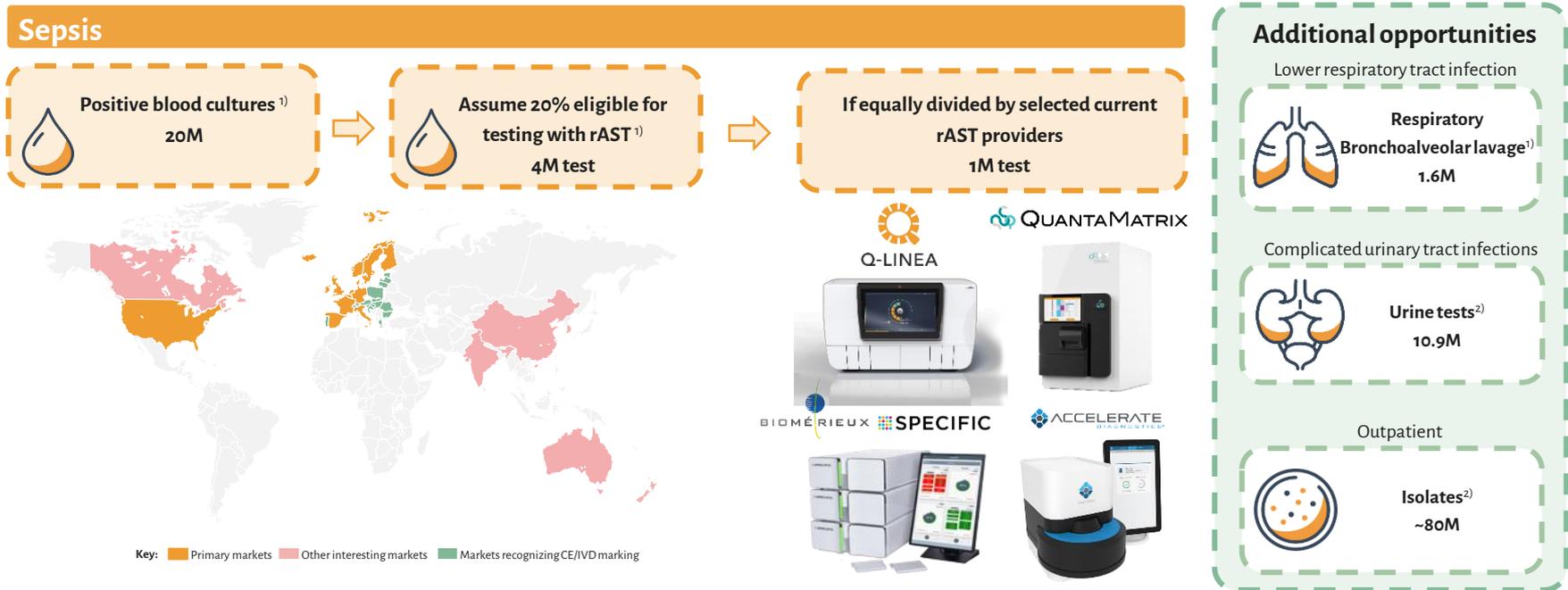
# Up to 48 hours faster actionable results



Time to Actionable results is what matters for septic patients

# Large addressable market for rAST from blood cultures

And large follow-up market for other samples



Source: Management account on estimated annual addressable market volume, US + CE + APAC, estimated volume in 2025

<sup>1)</sup> Blood from positive blood culture

# ASTar bring a broad panel, full automation and ease of use in one system

Time to actionable results is key in sepsis diagnostics

**Fully-automatic:**

QANTAMATRIX      Q-LINEA      ACCELERATE DIAGNOSTICS

**Semi-automatic:**

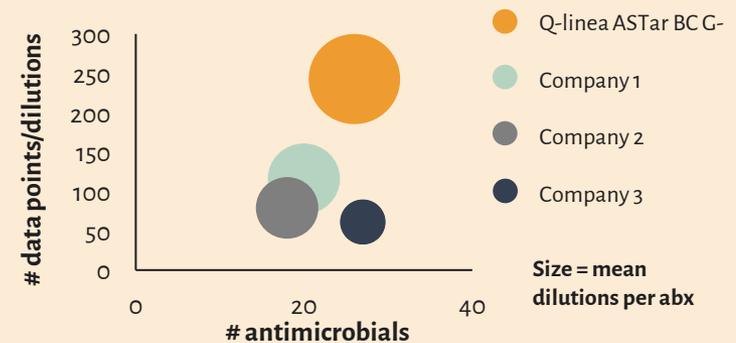
BIOMÉRIEUX      SPECIFIC



## ASTar combines:

- Fully-automatic. Less than 2 min hands-on time
- Random access
- High throughput – 12 samples in parallel
- Fastidious & non-fastidious bacteria

With the broadest G- panel (antibiotics & ranges) & flexible consumable support!



# Commercialisation footprint – 2023 was important to create a strong footprint in EU and the USA

We started 2023 with commercial activity in Sweden – and with a competitive product



We closed 2023 with a strong distribution network in all key geographies in EU and with two subsidiaries in Italy and USA



# AStar performs well in customer evaluations

## rAST is a new field in Europe and all customers want to try before they commit

**FR**

*"AStar seems to be efficient and reliable compared to standard AST techniques, and the results allows/enables rapid adjustment of antibiotic therapy. These first encouraging results should be supplemented by studies on a larger number of strains"* (translated to English from French by Q-linea)

Ponderland L. et al, P-047 RICAI 2022  
Laboratoire de Bactériologie-Hygiène Hospitalière, Centre Hospitalier Universitaire Grenoble Alpes, Grenoble, Bacterial Pathogenesis and Cellular Responses, Institut de Biologie Structurale, CEA-CNRS-UGA, Grenoble, France

**UK**

*"The AStar system represents an exciting innovative platform with potential for significantly decreasing the interval to antimicrobial optimization in blood stream infections. The potential clinical impact is greatest in pathogens with unpredictable antibiograms like those we encounter locally in our Gram-negative pathogens. Its impressive performance is also combined with ease-of-use and low hands-on-time for the lab technician which are benefits that are often overlooked."*

-Stephen P Kidd, Lead Healthcare Scientist, PhD, Hampshire Hospitals NHS Foundation Trust, UK

**DE**

*"The use of AStar significantly shortened the time from BC sampling to the delivery of the antibiogram to the attending physician when compared to the VITEK 2 system from 5 h short-term cultures."*

Jan Esse et al., J Clin Microbiol 2023 Nov; 61(11): e00549-23  
Mikrobiologisches Institut - Klinische Mikrobiologie, Immunologie und Hygiene - Universitätsklinikum Erlangen and Friedrich-Alexander-Universität (FAU) Erlangen-Nürnberg, Erlangen, Germany

**UK**

*"Automated reading of results – significantly reduces the risk of reporting incorrect results due to human error."*

Joanne Bullivant et al, Poster ECCMID 2022  
Sheffield Teaching Hospital NHS Foundation Trust (STH), Sheffield, UK

**FR**

*"AStar delivers rapid MIC results compared with other rapid antibiogram methods. Expanding the panel with Gram-positive bacteria (staphylococci, streptococci, etc.) as well as additional Gram-negative bacilli (Stenotrophomonas, maltophilia, Campylobacter spp., Salmonella sp, etc.) would be an additional advantage.... The clinical impact of this new AST method must be evaluated to find its place in clinical laboratory practice."* (translated to English from French by Q-linea)

Valentine Berti et al, P-048 RICAI 2022  
Service de Bactériologie, Hôpitaux Saint-Louis-Lariboisière-Fernand Widal, AP-HP Paris France

**SE**

*"AStar is a user-friendly system and has a broad panel of antimicrobials for gram negative bacteria"* (translated to English from Swedish by Q-linea)

Alisa Rizvanovic et al, Poster Vårsmötet 2023  
Klinisk Mikrobiologi, Medicinsk Diagnostik Karolinska, Karolinska Universitetssjukhuset, Stockholm, Sverige

**FR**

*"The performance of this system is high, and could add value for early detection of Multi-Drug Resistant or Extensively Drug Resistant Gram-negative bacteria in sepsis"*

Hélène Pailhories et al., P0189 ECCMID 2023  
Laboratoire de Bactériologie, CHU Angers and Laboratoire HFH, Université d'Angers, France

**UK**

*"Patients may currently be on empiric treatment for 48 hours before we can change that treatment. AStar has the potential to reduce that, even by 24 hours that is a massive impact"*

Chloe Hyton, Senior Biomedical Scientist Microbiology, Whiston Hospital UK

**FR**

*"Based on these findings, AStar may be a valid laboratory tool for rapid AST of BSI-causing Gram-negative bacteria."*

Giulia De Angelis et al., P0319 ECCMID 2023  
Università Cattolica del Sacro Cuore, and Policlinico Universitario Agostino Gemelli IRCCS, Rome Italy

**BE**

*"Overall, AStar" provides the microbiology laboratories and physicians with a fast tool for AST directly from blood cultures with minimal hands-on time and fully automated measurement."*

Kim Callebaut et al., Oral presentation ECCMID 2023  
Universitair Ziekenhuis, Brussels, Belgium

**UK**

*"Medical Lab Assistant and Associate Practitioner staff are capable of using instrument with ease, reducing pressure on Biomedical Scientists."*

Jennifer Monkhouse et al, Poster IBMS 2023  
Mersey and West Lancashire Teaching Hospitals NHS Trust, UK

**"AStar fits right into our processes and systems"**

Robert Price, Senior Biomedical Scientist, Whiston Hospital, UK

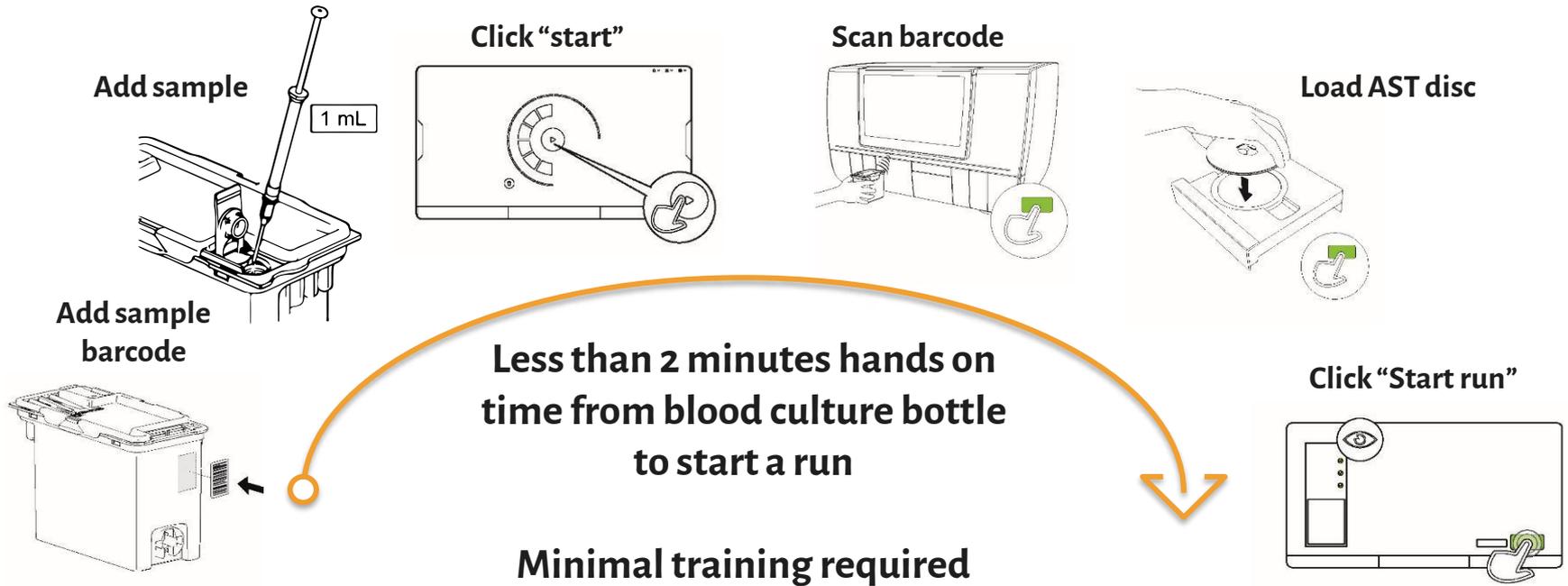
**Large multicentre evaluation in Germany and UK**

Covered 500 AStar determinations on routine clinical samples Compared against both Sensititre™, Vitek® and multipoint

**AStar's panel covered 98.7% of all organisms included in the study**



# ASTar enables anyone at the lab to load samples anytime



Source: Company information and webpage

# ASTar EU-IVDR Gram negative panel – the broadest AST panel in EU\*

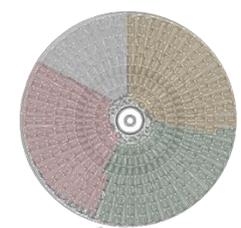
Antimicrobial class	Antimicrobial agent	C. freundii	C. koseri	E. cloacae complex	E. coli	K. aerogenes	K. oxytoca	K. pneumoniae	M. morgani	P. mirabilis	P. vulgaris	S. marcescens	P. aeruginosa	A. baumannii
<b>Non-fastidious</b>														
Penicillin	Ampicillin				•					•				
Penicillin	Amoxicillin-clauvulanic acid		•	•		•	•			•	•			
Penicillin	Piperacillin-taxobactam	•	•	•	•	•	•	•	•	•	•	•	•	
Cephalosporin	Cefazolin				•									
Cephalosporin	Cefepime	•	•	•	•	•	•	•	•	•	•	•	•	•
Cephalosporin	Cefotaxime	•	•	•	•	•	•	•	•	•	•	•		
Cephalosporin	Cefoxitin				•	•	•		•					
Cephalosporin	Ceftazidime	•	•	•	•	•	•	•	•	•	•	•	•	
Cephalosporin	Ceftazidime-avibactam	•	•	•	•	•	•	•	•	•	•	•	•	•
Cephalosporin	Ceftazidime-tazobactam	•	•	•	•	•	•	•	•	•	•	•	•	•
Cephalosporin	Ceftriaxone	•	•	•	•	•	•	•	•	•	•	•		
Cephalosporin	Cefuroxime				•	•	•		•					
Carbapenem	Ertapenem	•	•	•	•	•	•	•	•	•	•	•		
Carbapenem	Meropenem	•	•	•	•	•	•	•	•	•	•	•	•	•
Monobactam	Aztreonam	•	•	•	•	•	•	•	•	•	•	•	•	
Fluoroquinolone	Ciprofloxacin	•	•	•	•	•	•	•	•	•	•	•	•	•
Fluoroquinolone	Levofloxacin	•	•	•	•	•	•	•	•	•	•	•	•	•
Aminoglycoside	Amikacin	•	•	•	•	•	•	•	•	•	•	•	•	•
Aminoglycoside	Gentamicin	•	•	•	•	•	•	•	•	•	•	•	•	•
Aminoglycoside	Tobramycin	•	•	•	•	•	•	•	•	•	•	•	•	•
Tetracycline	Tigecycline		•											
Miscellaneous agent	Colistin				•			•						
Miscellaneous agent	Trimethoprim-sulfamethoxazole	•	•	•	•	•	•	•	•	•	•			

Antimicrobial class	Antimicrobial agent	H. influenzae
<b>Fastidious</b>		
Penicillin	Ampicillin	•
Penicillin	Amoxicillin-clauvulanic acid	•
Cephalosporin	Cefotaxime	•
Cephalosporin	Ceftriaxone	•
Carbapenem	Meropenem	•
Fluoroquinolone	Levofloxacin	•

**ASTar AST disc:**

336 reaction wells in a 120 mm CD format.

10 different sectors  
i.e. fastidious and non-fastidious conditions.



ASTar Instrument and ASTar BC G- Kit are CE IVDR-marked but not FDA 510(k)-cleared and not available for sale in the United States.  
\*Company information based on competitor analysis January 2025 and with regards to number of antibiotics and concentration ranges



## ASTar wins the first public tender for rAST in Italy

Tor Vergata tender outcome,

	Quote value €	Financial score	Technical score	Total score	Rank
bioMérieux	439,619	30	52.13	82.13	2
Quantamatrix	588,750	22.4	49.6	72	3
Accelerate Diagnostics			0		n.a.
<b>Q-linea</b>	<b>598,000</b>	<b>22.05</b>	<b>64.83</b>	<b>86.88</b>	<b>1</b>

### The rAST market is starting to move in Europe

Today more than 15 rAST systems are in tender preparation or has been recently announced

Italy is moving first, driven by high patient need and early Q-linea activities to open the market



## *The US market is coming closer*

FDA discussions indicates that we are coming closer to clearance (approval)

- Final details are discussed but no major questions or concerns

Most important market due to size and demonstrated to be more mature for rAST than Europe

- Two Early Access customers and several in pipeline
  - Positive initial feedback
  - Important to build the US market in 2024
  - Similar strategy as Europe – let ASTar perform in hands of key market leaders

Will initially be approached using internal sales force & regional office

- Discussions with distribution partnership ongoing to extend coverage

In final stage for New-Technology-Add on Payment (NTAP) application

- If approved, it would enable customers to receive dedicated and additional reimbursement when using ASTar
- Will be valid for three years
- NTAP application was enabled by FDA breakthrough device classification of ASTar

## *Way forward for Podler*

Several business opportunities are being evaluated



### **After the period end the board decided to place the Podler asset in a separate company**

- Fully owned subsidiary
- Purpose is to enable continuation of ongoing business discussions
- Enable separate focus for both for Podler and ASTar
- Maximize value for Q-linea shareholders

*We are expecting an interesting conference at AMCLI*

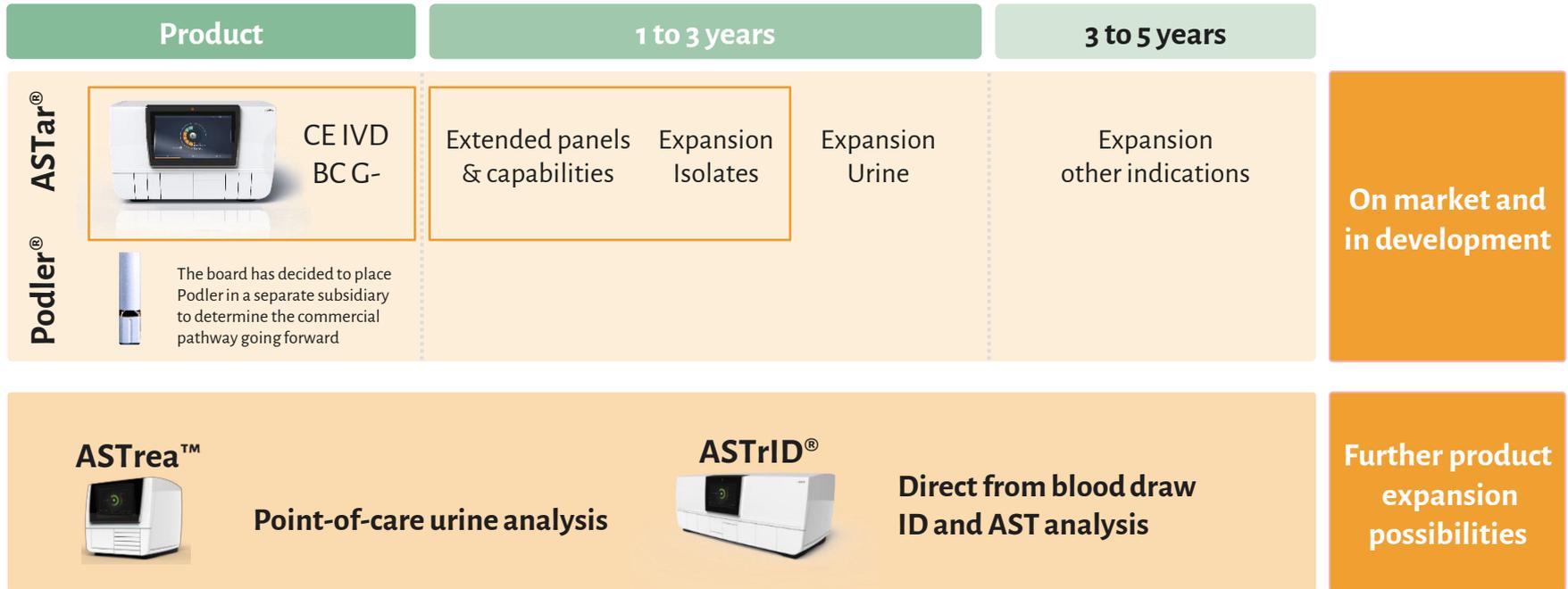
Q-linea will host a workshop at Italian Association for Clinical Microbiology

## Two interesting session at the workshop 9<sup>th</sup> March 2024

- **Prof. Alexia Verroken, from Cliniques Universitaires Saint-Luc, Brussels**
- Comparative analysis of Q-linea's ASTar system with two other rapid AST technologies, providing insights into user-friendliness, performance, and clinical impact of each approach.
- **Prof. Maurizio Sanguinetti, from Università Cattolica del Sacro Cuore, Rome**
- Presentation of interim data from the ongoing Lifetimes health economics study, including 160 prospective ICU patients with bloodstream infections.



# Unique technology enables disruptive expansion pipeline & opportunities



Source: Company data

## Consolidated statement of profit and loss

### Fourth quarter:

- Lower sales than anticipated due to slower conversion of sales funnel/longer lead times
- Operating result SEK -55,4 million (-59,6) or -18.5M on average per month
  - -19.5M on average for the first nine months
  - Improvement thanks to lower “Other external expenses”
- Improved financial net (excess cash invested, higher interest rates)
- The company reported a loss after tax of SEK -54.2 million (-63.7)
  - -229.4 (-268.7) for the full year
- Earnings per share amounted to -0.46 (-2.18), before and after dilution
  - -2.18 (-9.20) for the full year 2023

*Figures in parentheses refer to the outcome for the corresponding period in the preceding year with respect to earnings and cash flow and to the closing balance in the preceding financial year with respect to the balance sheet.*

## *Consolidated statement of financial position - end of fourth quarter*

- Cash and cash equivalents amounted to SEK 81.9 million (72.9)
- Remaining loan facility from main owner of SEK 41.5 million (0)
  - **Total: SEK 123.4 million available funds Dec 31, 2023.**
- Inventories amounted to SEK 46.5 million (42.3)
  - Instruments large part
- Equity amounted to SEK 189.6 million (163.2)

*Figures in parentheses refer to the outcome for the corresponding period in the preceding year with respect to earnings and cash flow and to the closing balance in the preceding financial year with respect to the balance sheet.*

## *Future financing*

- Q-linea does not yet generate positive cash flow from its operations
- Q-linea reported that we do not have “going concern”
- As previously stated we have a total of SEK 123.4 millions in available funds at year end and an average operating result of SEK -18.5 million in the fourth quarter.
- A large restructuring (cost savings plan has been implemented, full effect as from Q3 2023
- Early commercialisation phase → Engaged in pursuing alternative financing options
  - Licensing of distribution and sales rights
  - Strategic partnerships
  - Capitalisation of existing assets within Q-linea
  - Negotiations with new and existing investors, financiers, lenders
- **It is the BoD assessment that the group successfully will be able to finance company operations going forward**

*Thank you!*



**Q-linea wants to contribute to a healthier society by future-proofing a new generation of healthcare professionals, labs and hospitals**