

Q-LINEA

Sustainable healthcare for a new generation

Presentation Q1(24)

May 31, 2024



Key messages for today



- 1 **FDA clearance in April** has enabled full commercial activities in US market and expanding opportunity pipeline
- 2 **Strong clinical results** from Q-linea's scientific partners were presented at leading scientific conferences
- 3 **Cost saving program successfully completed** and will generate run-rate savings of SEK 50 million annually
- 4 **Additional financing secured** with a loan facility from Nexttobe (Q-linea's largest shareholder): total value SEK 101.5 million

Q1 highlights | Progress against top priorities with breakthrough on FDA approval

Overall, solid progress on top priorities for first 90 days in-role as CEO

Commercial Acceleration

- First commercial shipment of ASTar instrument (Italy)
- Strong reception for initial clinical results presented at AMCLI and ECCMID
- Expanding pipeline in US following FDA approval; and across Distributor markets in Europe

Innovation and Product Development

- FDA approval achieved! (April 26)
- Pre-submission of v2 menu for US market; expanded range of drug-bug combinations
- Focused R&D efforts on further improvements to ASTar software capabilities and menu expansion, e.g., BC G+

Organisational Readiness

- Restructuring process complete; savings secured from July onward
- Consolidation of staff at Uppsala Science Park campus to a single office following restructuring
- 3PL logistics established for US market to support commercial shipments

Financial Health

- Overall result ahead of plans – cost saving program delivering early results
- Focus is on driving topline growth; anticipating additional tender wins
- Financing secured with loan facility totalling SEK 101.5m

Live in the USA! | FDA clearance for ASTar awarded on April 26, 2024

Most comprehensive panel with 18 antibiotics and 12 microbial species; 7 – 11 two-fold dilutions per antibiotic

ASTar v1 US menu

Antimicrobial class	Antimicrobial agent	Reportable range (mg/L)	<i>A. baumannii</i>	<i>C. freundii</i>	<i>C. koseri</i>	<i>E. cloacae</i> complex	<i>E. coli</i>	<i>K. aerogenes</i>	<i>K. oxytoca</i>	<i>K. pneumoniae</i>	<i>P. aeruginosa</i>	<i>P. mirabilis</i>	<i>P. vulgaris</i>	<i>S. marcescens</i>	Dilution steps
Non-fastidious															
Penicillin	Ampicillin	≤1 to ≥128					•					•			7
β-lactam combination agents	Ampicillin-sulbactam ¹	≤1 to ≥128 ⁶					•	•	•		•	•	•		7
β-lactam combination agents	Ceftazidime-avibactam ²	≤0.125 to ≥64	•	•	•				•		•		•		9
β-lactam combination agents	Meropenem-vaborbactam ³	≤0.25 to ≥64	•	•	•	•	•	•	•		•		•		8
β-lactam combination agents	Piperacillin-tazobactam ⁴	≤0.25 to ≥12		•		•				•	•	•	•		11
Cephalosporin	Cefazolin	≤0.25 to ≥32								•					7
Cephalosporin	Cefepime	≤0.25 to ≥128	•			•	•	•	•	•	•	•	•		9
Cephalosporin	Cefuroxime	≤1 to ≥128				•		•	•		•				7
Cephalosporin	Ceftazidime	≤0.25 to ≥128				•	•	•	•		•	•	•		9
Monobactam	Aztreonam	≤0.25 to ≥128			•	•	•	•	•		•	•	•		9
Carbapenem	Meropenem	≤0.06 to ≥128	•	•	•	•					•	•	•		11
Aminoglycoside	Gentamicin	≤0.25 to ≥64	•	•					•	•	•	•	•		8
Aminoglycoside	Tobramycin	≤0.06 to ≥64	•	•	•	•				•		•	•		10
Aminoglycoside	Amikacin	≤0.5 to ≥256	•		•		•	•	•	•	•	•	•		9
Tetracycline	Tigecycline	≤0.03 to ≥32	•	•	•	•	•	•	•				•		10
Fluoroquinolone	Ciprofloxacin	≤0.125 to ≥16		•	•	•	•	•	•	•	•	•	•		7
Fluoroquinolone	Levofloxacin	≤0.125 to ≥32	•	•	•	•	•	•	•	•	•	•	•		8
Miscellaneous	Trimethoprim-sulfamethoxazole ⁵	≤0.06 to ≥16				•	•	•	•				•		8

¹ Ampicillin-sulbactam in the ratio 2:1

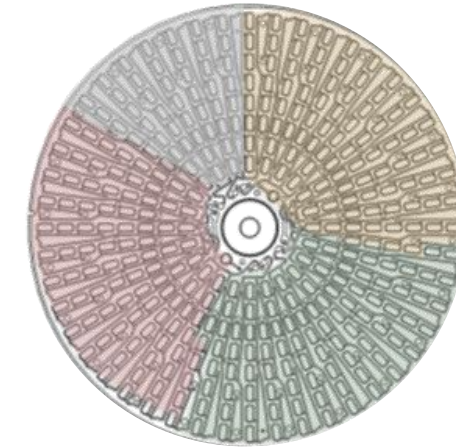
² For susceptibility testing purposes, the concentration of avibactam is fixed at 4 µg/mL

³ For susceptibility testing purposes, the concentration of vaborbactam is fixed at 8 µg/mL

⁴ For susceptibility testing purposes, the concentration of tazobactam is fixed at 4 µg/mL

⁵ Trimethoprim:sulfamethoxazole in the ratio 1:19

⁶ AST Reportable range for *P. vulgaris* is ≤2 to ≥128 µg/mL



The ASTar AST disc:

336 reaction wells in a 120 mm CD format.

10 different sectors

Enables unparalleled flexibility for differentiated assays, e.g., fastidious and non-fastidious conditions, and additional drug-bug combinations in future

AS^Tar: Revolutionizing AST

~6

**Hours
turn-around time**

- Save lives
- Save money
- Reduced effort

~2

**Minutes
Hands-on time**




- Simple interface
- Load-and-Go
- Minimal training need

1st

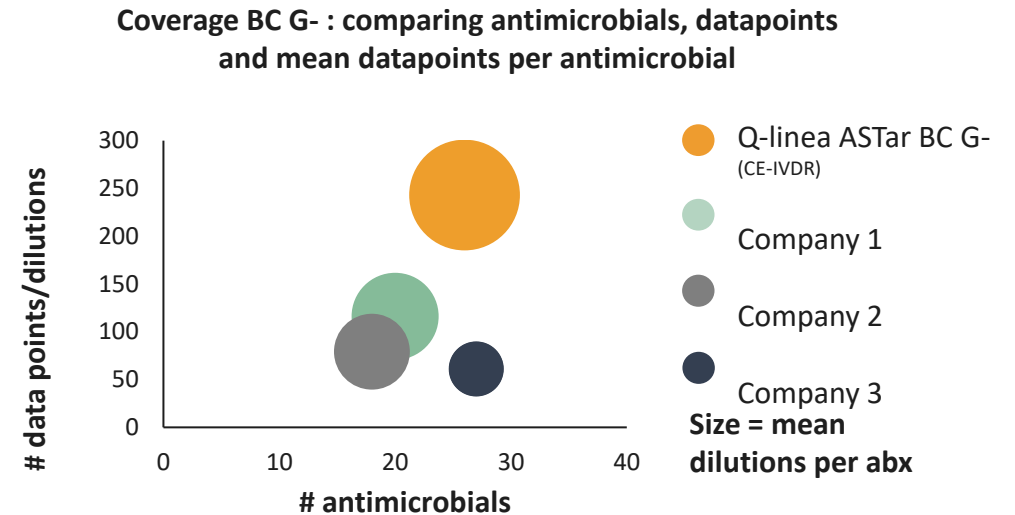
**Fully-automated,
random access platform**

- Comprehensive menu
- High reproducibility
- High throughput with 12 samples in parallel

Excellent and accurate data as evidenced from the US FDA Clinical Study

FDA and ISO requirements ^{1,2)}		
Essential agreement = Same MIC value as reference		
FDA	ISO	Q-LINEA 
89.9%	90%	95.2%³
Categorical agreement = Correct treatment recommendation		
FDA	ISO	Q-LINEA 
89.9%	90%	96.2%³
Reproducibility		
FDA	ISO	Q-LINEA 
95%	95%	99.3%³

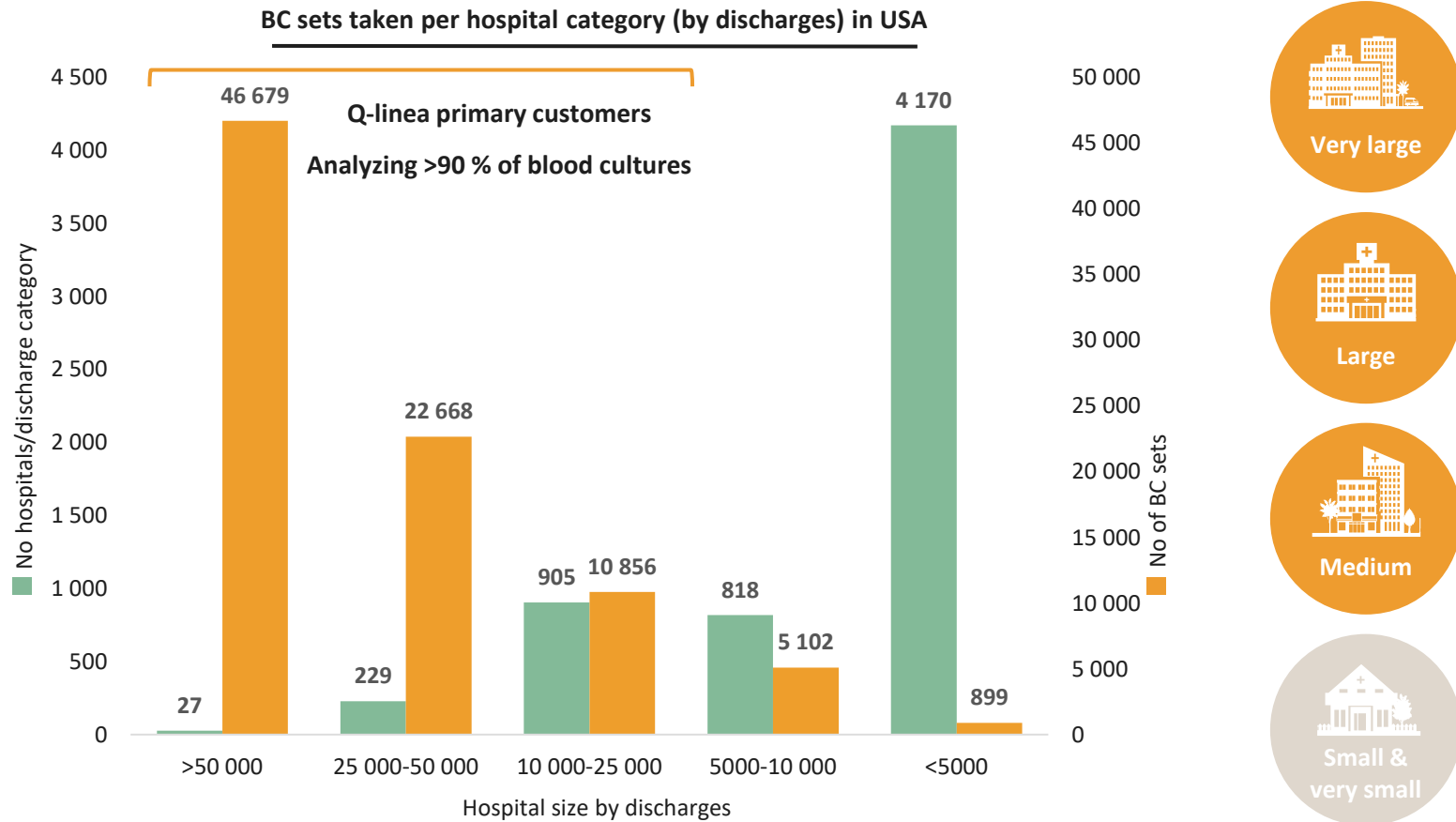
The ASTar® Instrument and ASTar® BC G- Kit offer the **broadest combination of antimicrobials and dilution ranges** in a single analysis for Gram-negative bacteria⁶. The analysis also **delivers true MIC results**



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) Data from FDA 510(k) SE Decision Summary https://www.accessdata.fda.gov/cdrh_docs/reviews/K221688.pdf

~20m patients in US | ASTar optimized for labs covering >90% of PBCs

ASTar target market of 1,200 – 1,600 US hospitals & labs



ASTar is optimised for mid-to-high volume labs

- Simple & easy workflow
- Very limited hands-on time (<2mins)
- Random & continuous access (add patient at any time)
- Up to 12 concurrent tests running
- High daily throughput

Source: "Clinical Values 2018 and Company Internal data"

ESCMID 2024 | Q-linea stepped out with FDA announcement in Barcelona

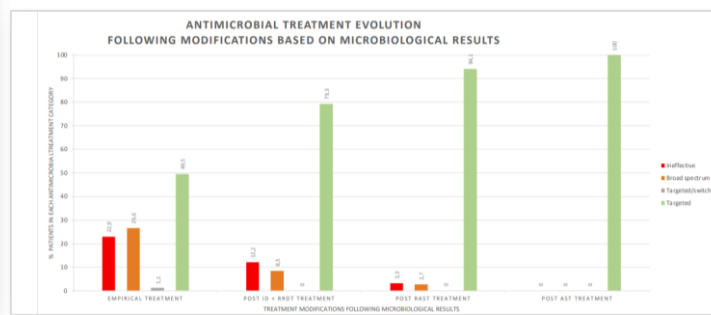
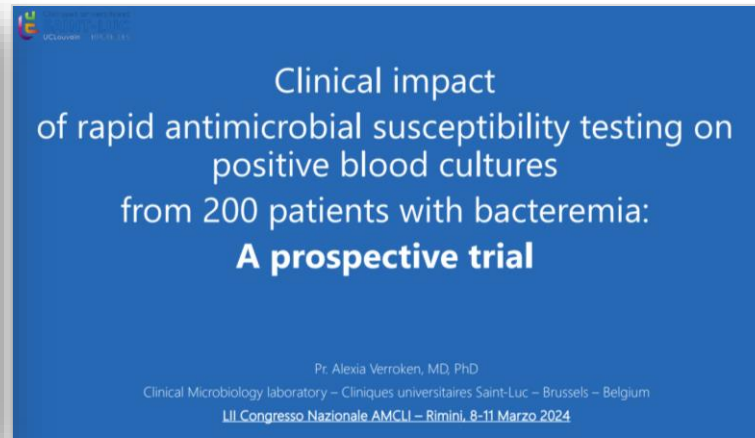


- **Largest microbiology conference** globally
- **Rapid AST emerged as a theme** with numerous clinical seminar sessions and scientific posters focused on the need and impact of rAST
- **Q-linea hosted poster sessions** to highlight findings from our ongoing clinical studies
- **High level of interest in Q-linea** from end-users (labs, physicians) and prospective distribution partners

Clinical evidence growing | Early results very strong, more studies coming

Q-linea sponsored studies generating strong initial results

Presented at the AMCLI Congress (Mar 2024) and ESCMID (Apr 2024)



Preliminary LIFETIMES study results

20-34 hours
Faster time to optimized therapy

45%
of patients with adjusted therapy

46%
of the antibiotic changes were escalations

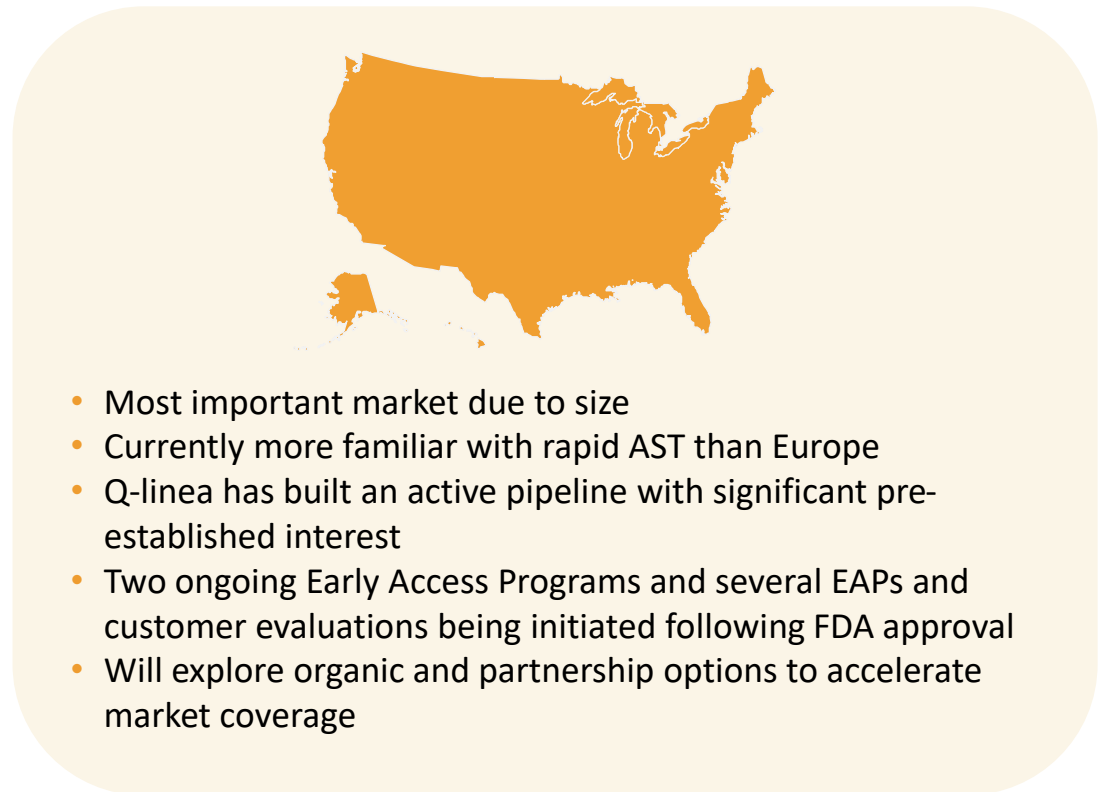
Commercial efforts | Accelerating in priority markets

Focus is on building and converting near-term pipeline; discussions with partners in 'next wave' markets ongoing

Active in key geographies in Europe with high AST need, either direct or using partners

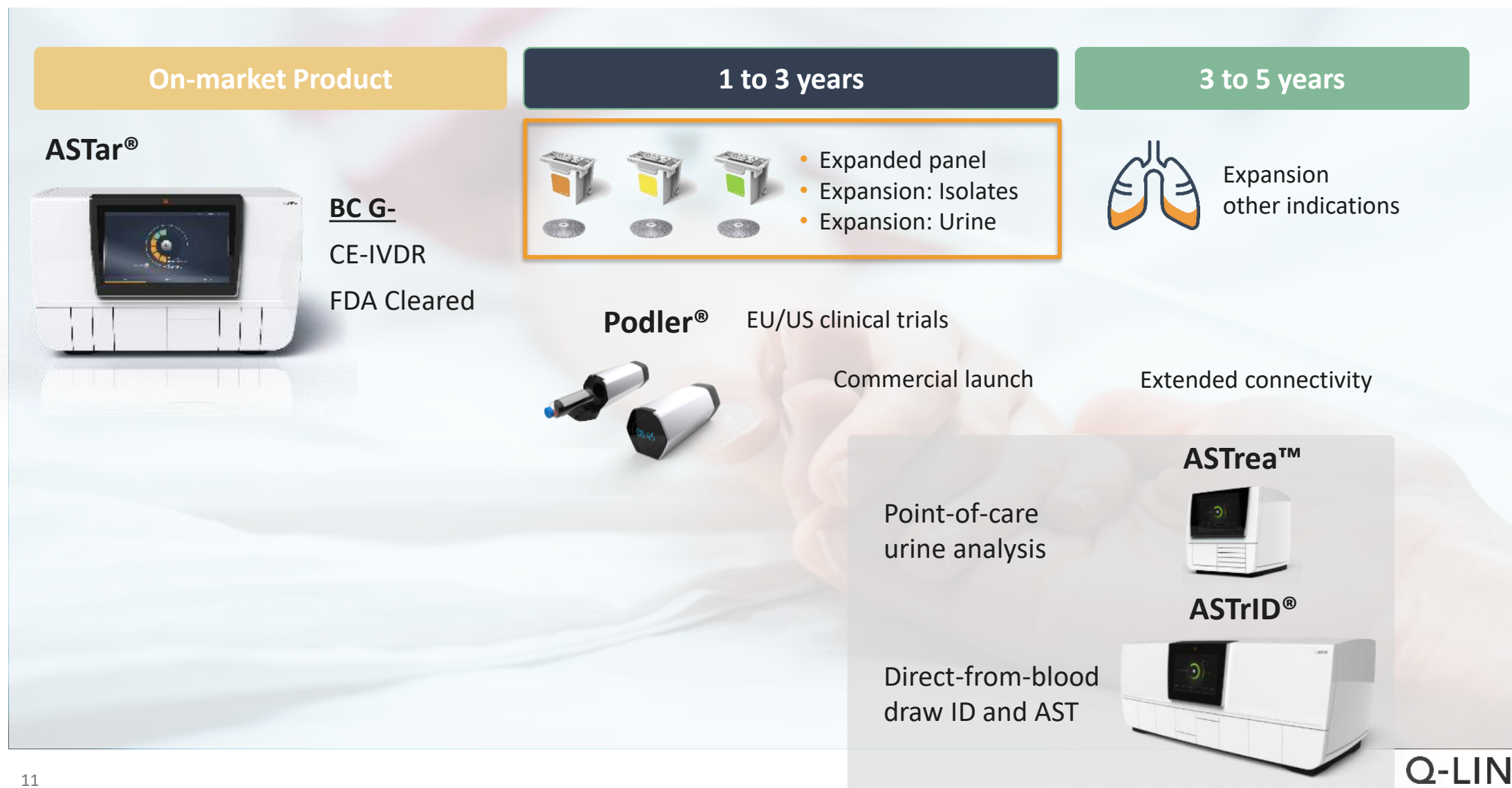


US commercial operations now fully active following FDA approval



Source: Company information

Focused innovation | Prioritising expansion of ASTar capabilities in near-term



Podler | Portable blood culture solution valued at SEK 70 million

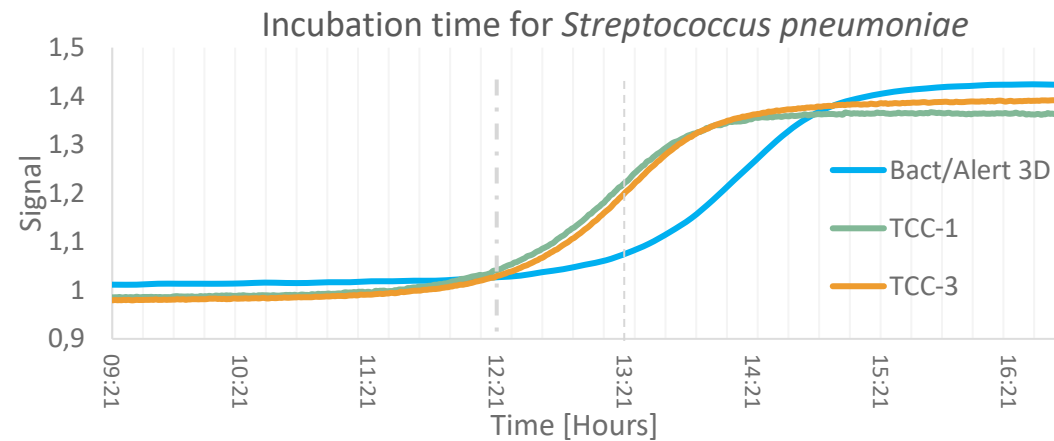
Will seek 3rd-party financing to take Podler to next level of development



Initiate incubation at point of collection

- Bring the microbiology to the patients
- Save >10 hours for blood culture results
- Enable more streamlined workflow in the lab
- **Use time instead of waste time**

Faster results compared to current SOC culture cabinet



Restructuring program | New organisation is live with full run-rate effect from July 2024

Q-linea implemented a cost saving program during H1 2024 with ambition to reduce SEK 50 million of annual spend

Program has been completed successfully with savings already being realised; full effect anticipated from July 2024 onward

Balance of spending now oriented to commercial activities with budgeted split:

- 1) **Supporting commercial activities** in key markets with emphasis on the US market following FDA clearance
- 2) **Expansion of AStar® testing menu** including additional drug-bug combinations, new offerings in e.g., isolate testing, Gram+ bacteria, additional specimen types, etc.
- 3) **Maintaining organisation and capabilities** through next phase of commercialisation
- 4) **Working capital to support instrument deployment** in reagent-rental contracts (i.e., razor-razorblade model)

Financial highlights | During (and after) first quarter

- Cost savings program initiated in January, estimated savings amount to SEK 50 million annually, restructuring costs of SEK 5 million
- Cost savings to have full effect as from Q3 2024
- Shift in spending from development to commercial, accelerated by FDA clearance
- Decision to transfer Podler technology in February to separate company (valued at SEK 70 million by external analysis firm, strengthens parent company equity)
- Additional loan facility offered by main owner Nexttobe (May 29), subject to approval by AGM 28 June
 - Existing, unutilized facility as of 31 March: SEK 41.5 million
 - Additional facility offered: SEK 60 million
 - Cash at bank as of 31 March: SEK 29.3 million---→Total: SEK 130.8 million
- Operating result for the first quarter of SEK -55.9 million or SEK -18.6 million per month, in line with Q4 2023 but SEK 6 million better than Q1 2023.

Consolidated statement of profit and loss | First quarter

- Instrument sales and other operating income recorded, SEK 2.9 million (0)
- Operating result SEK -55,9 million (-62,2) or -18.6M on average per month
 - Improvement thanks to cost saving program 2023
- The company reported a loss after tax of SEK -56.0 million (-61.4)
- Earnings per share amounted to -0.48 (-2.10), before and after dilution
 - Average no of shares 117,166, 372 (29, 537, 947)
- *Cost savings program announced in January already visible in Q1, but full effect in Q3*

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.

Source: Company information.

Consolidated statement of financial position | End of first quarter

- Cash and cash equivalents amounted to SEK 29.3 million (81.9)
 - SEK 17.5 million average monthly burn-rate
- Remaining loan facility from main owner of SEK 41.5 million (41.5)
 - **Total: SEK 70.8 million available funds as of 31 March 2024.**
- Inventories amounted to SEK 43.5 million (46.5)
 - Instruments constitute a large part
- Equity amounted to SEK 133.8 million (189.6)
 - SEK 18.6 million average monthly decrease
- *Equity runway longer than liquidity runway, increased loan facility (PR 29 May) from main owner
Nexttobe will balance runways.*

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.

Source: Company information.

Future financing

- As of 31 of March we have a total of SEK 70.8 million in available funds, whereof cash at bank 29.3M and 41.5M in an unutilized loan facility from main owner (SEK 15 million paid out May 13)
- Additional loan facility of SEK 60 million offered from main owner Nexttobe (PR May 29), subject to approval by the AGM. Existing and new loan facility proposed to mature 30 June 2026. Total facility will then amount to SEK 101.5 million
- Our average monthly operating result for the first quarter was SEK -18.6 million. Cost savings program (SEK ~50 million annually) will have full effect as from third quarter with restructuring costs taken in Q2
- Q-linea reported that we do not have “going concern”
- Q-linea is in an early commercialisation phase, now FDA cleared, where sales pipeline/funnel is growing in Europe and in the US but we have to be engaged in pursuing alternative financing options including;
 - 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*