FUTURE PROOF HEALTHCARE

A sustainable healthcare for a new generation

Presentation Q3(23)

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Q-LINEA

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Q-linea 3rd quarter

Headquarters, Marketing and demo lab, Consumable production in Uppsala


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

Implementation of new commercialisation strategy

- ASTar's commercial coverage is expanding into Finland and the Baltics
- Results are coming in strong from several customer evaluations of ASTar
- 2024 will be back-loaded due to long sales cycles
- Health Economy is ongoing in Italy.

Updating our 510(k) applications for US market approval

- Discussion with FDA has significantly intensified after the summer

Discussion regarding commercial opportunities for Podler

- Currently discussing different alternatives to capitalize on Podler

Lead product ASTar®

EU-IVDR

USD FDA
Breakthrough device

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Source: Company information.

Time to actionable results is important

Sepsis is the most common cause of death in our hospitals

More common than lung + prostate + breast-cancer **combined**

Accounts for approximate 30% of all deaths in the hospital

Most expensive condition to treat in the US. >27B USD[1)]

Time to correct treatment is critical!

7.6% decrease of survival rate for every hour of delay of effective therapy[2)]

Source: 1). http://www.hcup-us.ahrq.gov /reports/ statbriefs/sb204-Most-Expensive-Hospital-Conditions.pdf. 2). Kumar et al, Crit Care Med. 2006 Jun;34(6):1589-96

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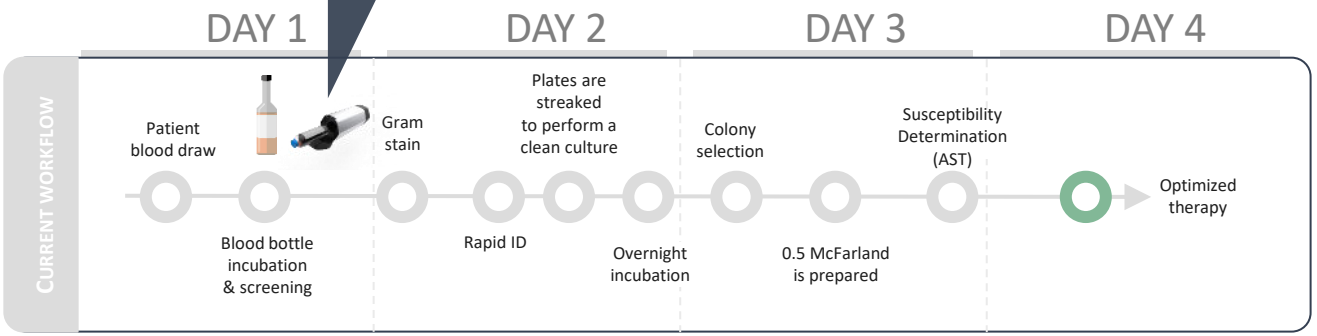
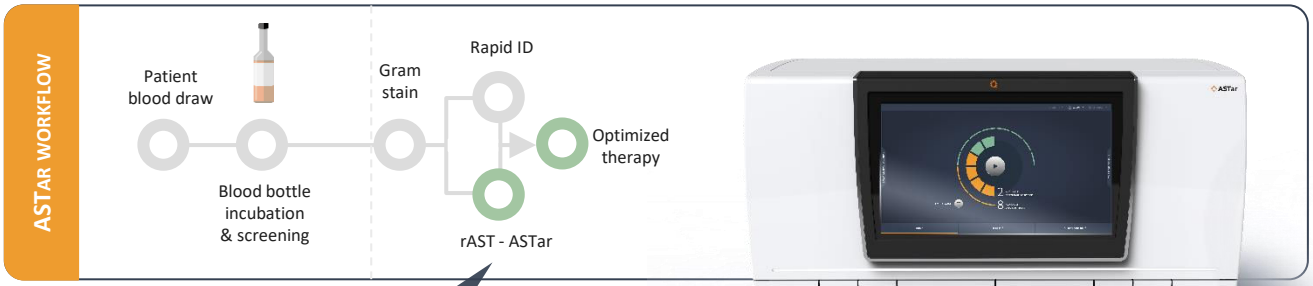
Rapid AST & a broad antimicrobial panel matters:
ASTar can provide up to 48 hours faster actionable results

Transportation of blood culture from patient to laboratory:
1 – 24+ hours





A broad panel, >25 antibiotics

Enable start of AST AND ID at the same time

Time to **Actionable** results is what matters for septic patients

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Tentative market for rAST from blood cultures in 2025

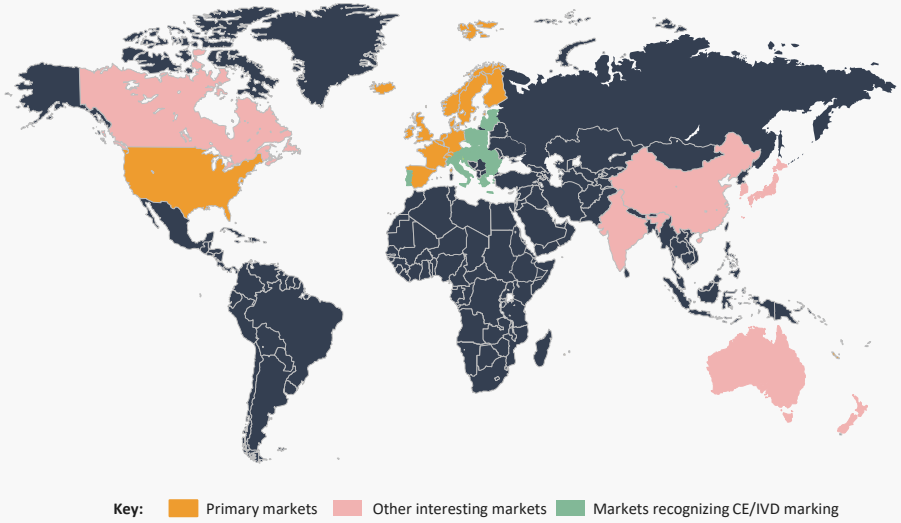
If one assumes that rAST is important for patients with Sepsis

Sepsis

Positive blood cultures [1]
20 M

Assume 20% eligible for testing with rAST [1]
4 M test

If equally divided by selected[2]
current rAST providers
1 M test



1) *Blood from positive blood culture. Source: Management account on estimated annual addressable market volume, US + CE + APAC,*
2) *Management selected rAST solution providers/systems.*

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Updated commercialisation strategy – summary so far

During 2023, we have significantly increased commercial footprint in Europe and have started in the USA

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PRO-LAB DIAGNOSTICS

Montebello DIAGNOSTICS

eurobio SCIENTIFIC

Labema

INTEGRA DIAGNOSTIC

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Goal is to demonstrate ASTar commercially
&
Enable a strong ramp-up in 2024

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Source: Company information

2023 goal is to set a foundation for successful 2024

Focus on coverage in Europe, approval in USA and performing customer evaluations

We see that the sales cycle is currently 9-15 months

- Initial discussion of interest to evaluate ASTar
- **Evaluation 1 to 2 months**
- **Analysis of workflow integration and performance, 2 to 4 months**
- Build internal business case to raise a tender, 1-3 months
- Budget allocation
- Tender process, 5-9 months

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ASTar performance is strong and it is easy to use

Evaluation of commercial systems for rapid antimicrobial susceptibility testing (rAST) of positive blood cultures: Comparison of susceptibility results

View Sheffield Hospital's scientific poster presentation from ECCMID 2022, featuring the ASTar System.

ASTar´s panel covered 95,4% of all organisms included in the study.

"ASTar fits right into our processes and systems"

Robert Price, Senior Biomedical Scientist, Whiston Hospital, 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 Hylton, Senior Biomedical Scientist Microbiology, *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.

Essential agreement (EA) >96,6%.

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Evaluation of the performance of ASTar in a 24/7 laboratory

Poster E0169 ECCMID 2023. Laboratoires de Bactériologie CHU Angers and Laboratoire HIFIH, Université d'Angers, France

Relevance

ASTar´s panel covered 96%[1] of all organisms included in the study performed at a 24/7 hospital setting with a **reduction in reporting from 16 h 33 min for SOC to 6h 19 min for ASTar**

Performance

98 % Categorical Agreement *with Standard of Care, after discrepancy testing*

Workflow

Standard of Care Rapid ID using MALDI-TOF was performed after a 5-hour growth on agar-plate, delivering ID results, ***well synchronized with ASTar results***

"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"[2]

Table 1 : Delays for AST results obtained by ASTar ® versus standard techniques

Technique	ASTar® on BCB	Standard techniques
Mean time for AST results	06 h 19 min	16 h 33 min
Minimum time for AST results	06 h 11 min	13 h 58 min
Maximum time for AST results	06 h 39 min	26 h 07 min

1. *50 of 52 consecutive samples reported by ASTar .The site selected Escherichia coli as ID for one (1) Salmonella enterica case to enable ASTar to report out the result. No discrepancy of results compared to SOC.*
2. *Extract of text from Conclusion section of poster E0169, ECCMID 2023*

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Evaluation of the performance of ASTar in a laboratory open 8 a.m. -18 p.m.

Esse et al. Journal of Clinical Microbiology 10.1128/jcm.00549-23

Relevance

ASTar´s panel covered 94%[1] of all organisms included in the study and with a **reduction from blood culture sampling to AST report from 44 h 18 min for SOC to 28 h 59 min for ASTar**

Performance

98 % Categorical Agreement *with Standard of Care, after discrepancy testing*

Workflow

Standard of Care Rapid ID using MALDI-TOF was performed after a 5-hour growth on agar-plate, delivering ID results, ***well synchronized with ASTar results***

"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. "[2]

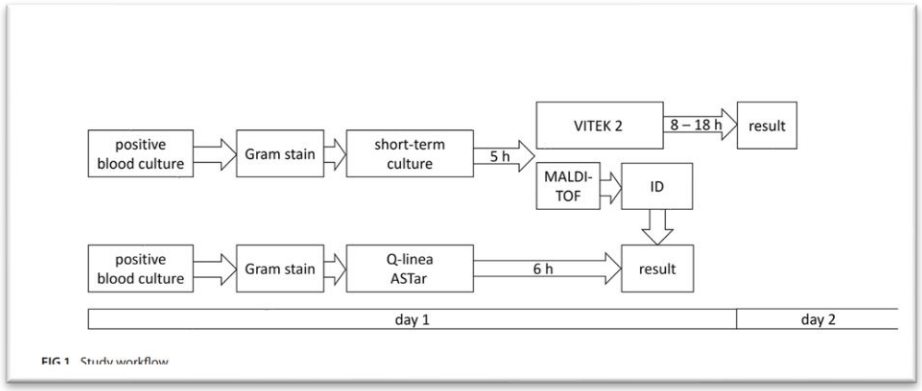

FIG 1 Study workflow

1. 51 prospective and 27 archived isolates
2. Extract of text from Conclusion section of 10.1128/jcm.00549-23

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Evaluation of the performance of ASTar on patients from ITU and ED

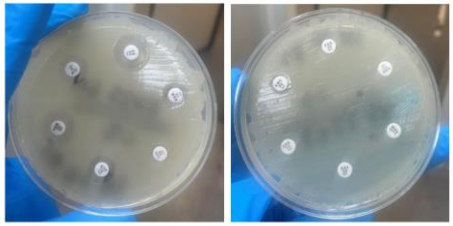
Poster IBMS_2023 HHFT Goring et al[1]

Relevance

"To complement categorial AST results the ASTar assay also includes MICs. ***Having this rapid detail can lead to further optimisation of treatment****."*

Performance

98 % Categorical Agreement *with Standard of Care*



Antimicrobial	MIC (mg/L)	Interpr
Amoxicillin-clavulanic acid	>32	R
Piperacillin-tazobactam	256	R
Cefazolin	>16	R
Cefepime	32	R
Cefotaxime	>128	R
Cefoxitin	>64	POS
Ceftazidime	>64	R
Ceftazidime-avibactam	>32	R
Ceftolozane-tazobactam	>32	R
Ceftriaxone	>128	R
Cefuroxime	>64	R
Ertapenem	2	R
Meropenem	2	S
Aztreonam	64	R
Ciprofloxacin	4	R
Levofloxacin	1	I
Amikacin	4	S
Gentamicin	32	R
Tobramycin	32	R
Colistin	0.5	S
Trimethoprim-sulfamethoxazole	>8	R

Disc diffusion plates with an NDM CPE *K. pneumoniae* and ASTar MIC results

1. https://qlinea.com/0986741_wp-uploads/2023/10/IBMS-2023-HHFT-ASTar-v2.pdf

"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. The demonstrable rapid clinical interventions can deliver significant benefits for individual patients and healthcare organizations in terms of quality of care, patient safety, antimicrobial stewardship, and infection prevention measures."*

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

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Evaluation of the performance of ASTar on patients from a Teaching hospital

Poster IBMS_2023 Monkhouse et al

Relevance

Expert rules and exceptional phenotypes are automatically applied [1]

Performance

98 % Categorical Agreement *with Standard of Care*

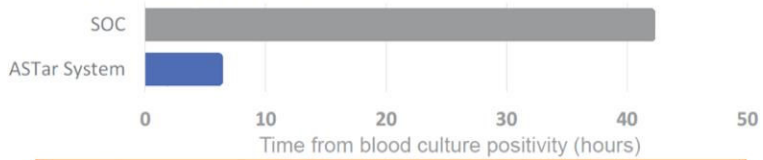
Workflow

Medical Lab Assistant and Associate Practitioner staff are capable of using instrument with ease, ***reducing pressure on Biomedical Scientists***[1]

"Reduces MIC turnaround time by at least half"[1]

RESULTS

Figure 4. Hours to actionable result from positive blood culture for traditional methods (SOC) vs ASTar®



Total no. of antibiotics tested		1375
Total no. discrepancies		35
Essential agreement (%)		97.5
Statistical Analysis (%)		
Accuracy	Sensitivity	Specificity
98	97	98

Table 1. Gold standard vs ASTar. Essential agreement (%) summary of 1375 datapoints

1. *Extract from Conclusions section of poster, Monkhouse et al, 2276 Timely targeted Treatment in Sepsis, IBMS 2023 Birmingham*

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Evaluation of ASTar in an endemic area for multi-drug resistant bacteria

P0319_ECCMID 2023 Angelis et al

Relevance

In the limited dataset, 4 out of 10[1] isolates had ***beta-lactamase resistance mechanisms***

Performance

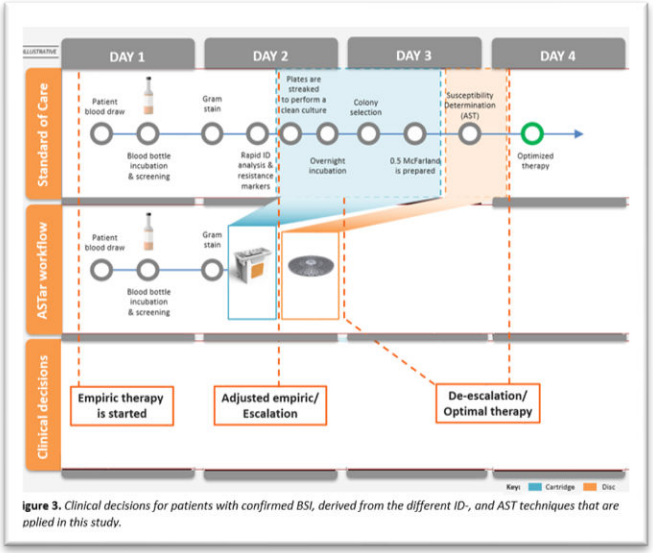
98 % Categorical Agreement *with Broth microdilution results*

A NEW ASSAY FOR RAPID ANTIMICROBIAL SUSCEPTIBILITY TESTING OF BLOODSTREAM INFECTION-CAUSING GRAM-NEGATIVE BACTERIA

Giulia De Angelis[1,2], Giorgia Sanna[1], Giulia Menchinelli[2], Silvia Zelli[1], Venere Cortazzo[1], Tiziana D'Inzeo[1], Barbara Fiori[2], Teresa Spanu[1], Brunella Posteraro[1,2], Maurizio Sanguinetti[1,2]

[1]Università Cattolica del Sacro Cuore, Rome, Italy; [2]Policlinico Universitario Agostino Gemelli IRCCS, Rome, Italy

"Based on these findings, ASTar may be a valid laboratory tool for rapid AST of BSI-causing Gram-negative bacteria. "[2]



igure 3. *Clinical decisions for patients with confirmed BSI, derived from the different ID-, and AST techniques that are pplied in this study.*

Study is part of the ASTar HEOR study Lifetimes

1. *Interim analysis, only 10 positive blood cultures included at time of publication*
2. *Extract of text from Conclusion section P0319_ECCMID 2023*

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Evaluation of rapid phenotypic AST methods for gram negative rods

Oral presentation ECCMID 2023, Callebaut et al

Relevance

Provide SIR interpretation and EUCAST expert rules automatically – as compared to RAST

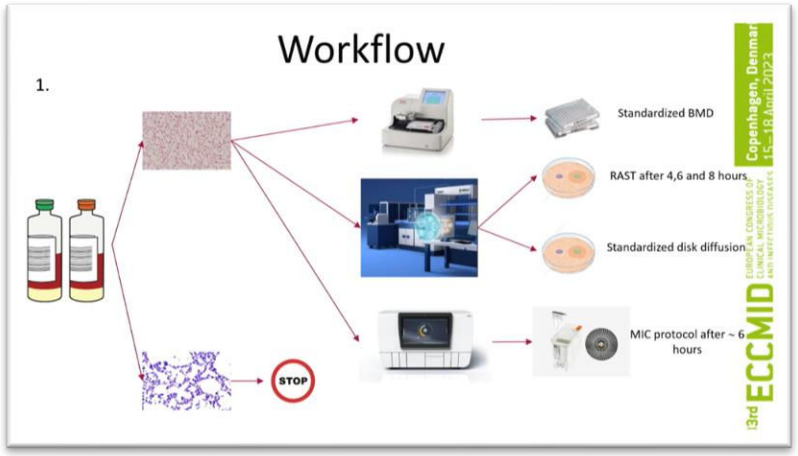
Performance

Good overall Categorical Agreement[1] *with Broth microdilution results, including challenge isolates*

Workflow

Concluded that if the lab would have been open, ***it would be easy to start an ASTar any time of the day*** *but consultation with physicians would still need to be solved to really utilize rapid AST*

"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. "[2]



1. *Data not to be shared until publication as wished by the authors*
2. *Extract of text from presentation Callebaut et al, oral presentation ECCMID 2023*

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2023 goal is to set a foundation for successful 2024

Focus on coverage in Europe, approval in USA and performing customer evaluations

In summary

- **All ASTar evaluations has been positive**
- **The value of rAST is clear**
- We have also seen value extending beyond correct and timely antibiotic treatment

  Reducing spread of bacteria between patients

- It will take some time before a customer will take a buy decision without evaluating first
- We have laid the foundation for 2024
- We expect to see commercial sales within last quarter

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The US market is coming closer

We are in active discussions with FDA

We submitted additional data for our US FDA 510k application in June

- We have during end of the 3rd quarter and into 4th quarter been in regular and frequent discussions with FDA
- We expect to submit our final 510k application during 4th quarter
- Time to clearance is difficult to predict, but we are coming closer to the US market

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Way forward for Podler

Several business opportunities are being evaluated

During the 3rd quarter the discussions on way forward for Podler have intensified

- We have received positive feedback from the US market
  - Trade shows
  - Direct customer discussions
- Discussions with several strategic collaboration partners during the period
- Several different business opportunities are currently being discussed
  - Collaborative development
  - Out licensing
  - Spin-out

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Financial highlights - third quarter

- Successful rights issue --- SEK 263 million before transaction costs
- Increase in number of shares from 29 537 947 to 117 166 372
- Lower costs thanks to cost saving program
- Decision to scrap LTIP program 2023/26

Source: Company information.

Consolidated statement of profit and loss - third quarter

- Net sales amounted to SEK 3.0 million (2.9) – on par.
- Operating result totalled SEK -48.2 million (-58.5) - improved.
- The company reported a loss after tax of SEK -48.6 million (-59.0).
- Earnings per share, before and after dilution amounted to SEK -0.56 (-2.02).

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.

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Source: Company information.

Consolidated statement of financial position - end of third quarter

- Cash and cash equivalents amounted to SEK 54.9 million (72.9).
- Short term investments SEK 80.0 million (0)
- Inventories amounted to SEK 43.4 million (42.3).
- Equity amounted to SEK 244.1 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.

Source: Company information.

Cash flow statement third quarter

- Cash flow from operating activities SEK -54.5 million (-53.7).
  On par with last year, 10M better operating result off-set by payments related to cost saving program

- Cash flow from investing activities SEK -79.5 million (64.6).
  Short term investments (bank risk) to return on liquid funds (divestment last year)

- Cash flow from financing activities SEK 163.9 million (-1.7).
  Rights issue less repayment of loan to principal owner (IFRS 16 lease amort last year)

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.

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Source: Company information.