FUTURE PROOF HEALTHCARE

A sustainable healthcare for a new generation

Presentation Q3(22)

Jonas Jarvius, CEO
Anders Lundin, CFO/IR

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

174 employees & consultants at quarter end

Very successful ID week conference in October

Discussions with FDA regarding 510k applications is ongoing

Q-linea successfully passes full IVDR certification in September

Q-linea and Thermo Fisher Scientific jointly agreed to end ASTar distribution partnership

Commercial discussions regarding Podler is continuing.

Lead product ASTar®

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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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Q-linea will be in control of marketing for all products

After discussions between the parties, a joint decision was taken to end distribution partnership.

Thermo Fisher Scientific decided to refocus on its core media business.
The view of ASTar has not changed and ASTar will be missed…

Sales targets are of course an integral part of an exclusive distribution partnership.
The 20 instruments sales to Thermo Fisher announced in May will be reduced to around 10.

All evaluations have been very successful and ASTar has performed as expected

Thermo Fisher Scientific and Q-linea will continue to work together with reference testing for clinical studies.

Commercial customers will be offered to be transferred to Q-linea.

Sales leads and ongoing evaluations will be transferred to Q-linea and Thermo Fisher will continue to support during the transition.

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Source: Company information.

Why did we not meet the sales targets?

We have analysed the launch in Europe and we have a couple of important lessons learned.

Rapid antibiotic susceptibility testing (rAST) is a young field in Europe.

The Corona pandemic has had continued effects during 2022 with stretched hospital budgets and limited staff availability.

Customers want to “try before you buy”.

How does the system perform in my clinical setting?

Customers are asking for clinical and health economic evidence (HEOR).

Customers wants to compare the different rAST solutions present in the market.

Voice of key opinion leaders and scientific evidence is important.

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Source: Company information.

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.

User testimonial;
How ASTar has helped save time in the lab

Listen to Ehsan Ghaderi, Head of Dept, and Sofia Persson, Consultant Physician, Bacteriology, Uppsala University Hospital, Sweden

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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Source: Company information.

Our plan for short and long-term for commercial success of ASTar

When launching a new product, we believe that a long-term strategy is important.

Increase awareness of rAST

Q-linea will actively support key opinion leaders and provide ASTar for evaluations.
Q-linea is in late-stage discussions to start evaluation studies of several rAST products.

“try before you buy”

Increase commercial footprint and accelerate evaluation and clinical evidence studies.

HEOR study is ready to start and waiting for the last ethical approval. ASTar instruments installed, training done.

Of course, we will immediately enter discussions with sales leads and evaluation customers that Thermo Fisher has built up.

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Source: Company information.

Our planned approach to the market

The collaboration with Thermo Fisher was a partnership, therefore Q-linea has mirrored Thermo Fishers sales & support organization and has participated during launch

Q-linea currently have a strong commercial and clinical value team.

15 persons in the commercial organization & 7 persons within clinical value.

We plan to expand the commercial team and focus on key geographies.

Use lessons learned from Europe and commercial adoption of rAST in USA.

USA is a clear focus

In discussions with two reputable hospitals that want to try ASTar before FDA approval

Make preparations to enable direct sales at launch.

Europe

Initial commercial coverage from Sweden.

Focus on building awareness, clinical & scientific evidence.

Focus on top three European countries first.

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Source: Company information.

Our planned approach to the market, cont.

We have a strong product and are investigating extending sales capabilities with commercial partnerships.

Q-linea has been approached by several large companies in the field within two days of the press release.

Commercial partnership with Thermo Fisher included only ASTar, therefore we have during the development of other products kept contact and discussions with other companies.

We are now evaluating of what strategy is the best to build company and shareholder value.

Source: Company information.

ASTar is coming closer to the US market & Q-linea is ready for the European market

Discussions are ongoing with FDA and Q-linea is currently awaiting feedback

Typically, an FDA approval will take 12-18 months
FDA has classified ASTar as a breakthrough device.

Q-linea passed IVDR audit performed by TÜV SÜD

Certificate will be issued during 2023
Q-linea will be one of the first in vitro diagnostic companies in Europe to achieve this milestone
This enables Q-linea both to release new products on the European market and make updates on current products.

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Source: Company information.

Podler discussions ongoing and capability build-up in production

Podler discussions are ongoing

Q-linea is in discussions around a potential commercial collaboration regarding Podler.

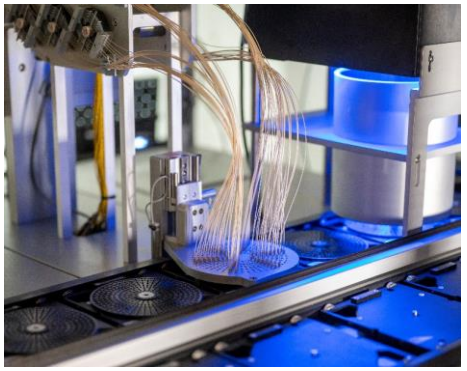
After changes in ASTar distribution, we are evaluating best commercial strategy for ASTar and Podler.

Build up in production capabilities for consumables has progressed well

A key manufacturing step for the ASTar consumables is the formulation and filling of the AST disc.

Q-linea is under late-stage verification of internally developed equipment for antibiotic manufacturing.

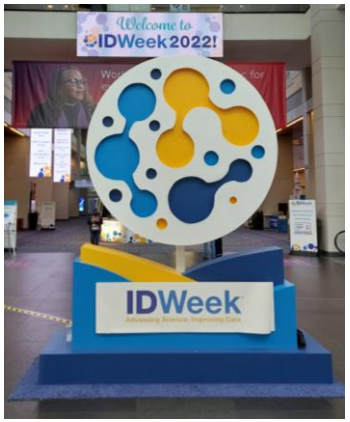
- Higher throughput
- Automatic quality control
- More efficient and uniform manufacturing process



Source: Company information.

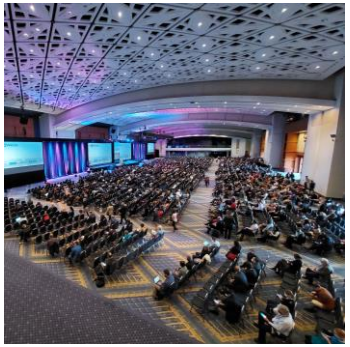
Key highlights after period end

ID week in Washington 19-23 October



Rapid AST was one of the key themes of the conference.

Antimicrobial Stewardship programs in the US much more broadly established and they see phenotypic rapid AST as one of the key needs to reduce time to optimal treatment.



Compared to Europe it is not so much a discussion about “why rAST” but rather “When” and “What technology”.

Several Hospitals expressed interested in running pre-FDA trials.

- Discussions with two reputable hospitals ongoing for pre-FDA evaluation.

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Source: Company information.

A pivotal development

Naturally, the separation from Thermo Fisher was not the plan, nor the intent when we enter the partnership two years ago.

However, Q-linea will now be in full control the commercial direction for both ASTar and other products and interest from other companies is strong.

It will be a transition period before we have fully implemented our new strategy.

We have a great product in ASTar as a solid base.

We have a clear view on what is needed in EU and USA to build future value.

We have commercial customers, a pipeline of evaluations and leads to build from.

We have continued support from Thermo Fisher during the transition.

I look forward to taking the next step in our journey together with all of you.

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Source: Company information.

Income statement third quarter

Net sales in the third quarter amounted to SEK 2.9 million (1.1).

Operating result totalled SEK -58.9 million (-50.0).

The company reported a loss after tax of SEK -59.4 million (-49.1).

Earnings per share, before and after dilution amounted to SEK -2.03 (-1.68).

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.

Balance sheet items at the end of third quarter

Cash and cash equivalents amounted to SEK 28.9 million (15.1)

Total Short-term investments amounted SEK 65.3 million (150.9) which pertain of the current portion of non-current assets (listed bonds).

Non-current assets, listed bonds SEK 63.2 million (181.8).

Inventories amounted SEK 22.3 million (28.6), includes a write-off of total SEK -4,0 (-4.7) million.

Source: Company information.

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.

Cash flow statement third quarter

Cash flow from operating activities SEK -55.4 million (-63.0).

Decrease in cash outflow from operating activities mainly due to favourable changes in the working capital compared to the same quarter last year which is partly offset by lower Operating result.

Cash flow from investing activities SEK 64.6 million (36.5).

Net divestment of Short-term interest funds in the quarter. Investments in mainly production equipment amounted SEK 0.9 (2.7) million

Cash flow from financing activities SEK 0 thousand (-0.1).

No cash flow from financing activities in the quearter

Cash and cash equivalents, Short term investments and listed bonds at the end of third quarter amounted **SEK 154.4 million** (347.8). The Board's assessment is that the **existing working capital do not cover the liquidity needed to conduct its planned operations for the next 12 months**. In light of the work being done to pursue potential financing options and recent developments at the Company, the Board considers the Company's prospects to finance its operations over the coming year to be favourable.

Source: Company information.

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.

Looking forward to an exciting continuation of 2022

Thank you

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