Interim report 1 January - 30 June 2024

ASTar launches in the US market

Second quarter: 1 April–30 June 2024

- Net sales amounted to SEK 0.2 million (1.4).
- The operating result totalled SEK -65.3 million (-64.6).
- The result for the period amounted to SEK -65.7 million (-65.0).
- Earnings per share before and after dilution amounted to SEK -0.56 (-2.23).
- Cash flow from operating activities totalled SEK -44.1 million (-53.5).

Period: 1 January–30 June 2024

- Net sales amounted to SEK 1.6 million (1.4).
- The operating result totalled SEK -121.2 million (-126.9).
- The result for the period amounted to SEK -121.7 million (-126.5).
- Earnings per share before and after dilution amounted to SEK -1.04 (-4.33).
- Cash flow from operating activities totalled SEK -92.0 million (-125.9).
- As of 30 June 2024, the Company had a total of SEK 20.9 million (81.9) in available funds.

Significant events

In the second quarter of 2024

- Q-linea receives US FDA 510(k) clearance for ASTar® on 26 April.
- The Company signs an evaluation contract with reference laboratory network in the US.
- Q-linea applies for an NTAP code for the US market.
- The Company holds 2024 Annual General Meeting on 28 June.
- Q-linea announces that the technology behind Podler has been valued at SEK 70 million. The valuation is based on a report carried out by an external analysis company.
- The Company is offered an extended loan facility by the principal owner Nexttobe of a maximum SEK 101,500,000. The loan facility runs until 30 June 2026 at the latest.
- Q-linea announces that CMS has determined that the ASTar system meets the cost criterion to qualify for NTAP funding.
- The Company receives another commercial order in Italy.
- Q-linea ships the first IVD-marked instrument to the US.

After the end of the period

- The Company participates in its first public tender in Belgium.

ASTar launches in the US market

Our commercialisation journey continued at pace through Q2 2024.

Stepping into the US market

Following on our FDA clearance at the end of April, the team has been actively engaging with customers across the US who are eager to evaluate the ASTar solution in their lab. Although we see our technology having relevance for more than 1,600 labs in the US, we are initially focusing our efforts on the top 100 labs with a track record of adopting technologies early and with the patient volumes to do so at scale. This will ensure the best use of our team resources while we plan for building up the team as volumes grow.

Positive signals from the CMS

Adoption of new technologies is sometimes gated by the availability of funding and reimbursement. We are therefore delighted that the ASTar system has been recommended by the Centers for Medicare & Medicaid Services (CMS) in the USA for a dedicated New Technology Add-on Payment (NTAP) code with reimbursement at USD 97.50 per patient. With our Breakthrough Technology designation from the FDA, we are hopeful that the CMS recommendation will be approved in the coming months. If approved, this additional funding will be available to labs treating Medicare patients that are tested on the ASTar system. This helps labs, which are often on tight operating budgets, to overcome the initial cost burden of taking on the technology which then has time to demonstrate the cost savings and health outcomes benefits.

Growing scientific and clinical interest

I have had the opportunity to speak with lab managers and clinicians from around the world at our main industry conferences held during this quarter in Barcelona and Atlanta. It is encouraging to witness the growing body of research in the field that points to the benefits of rapid AST, which continues to be a keynote topic at these events. In some markets, labs are encouraged by budget limitations to stratify their patient populations which potentially denies some patients the clinical benefits of new technologies. We will continue to work with our scientific partners to contribute to the body of evidence and raise awareness of these data so that policy makers and administrators can set guidelines and budgets appropriately.

Italy continues to set the pace in Europe

We were able to celebrate another instrument shipment to Italy this quarter, marking the culmination of an evaluation process that considered ASTar against the market alternatives. The clinical need for rapid AST is especially strong in Italy given the country's high rates of antimicrobial resistance (AMR). The clinical and financial benefits of the ASTar platform are therefore most immediately transparent to labs in the country, which is being demonstrated clearly through our pioneering work on health economics and outcomes research (HEOR studies) across four sites in Italy. However, the underlying growth in AMR is being felt across Europe, and around the world. We expect Italy to be a bellwether for the solutions that will be adopted more universally as AMR awareness grows.

Global opportunity for ASTar

We are seeing this growing awareness of AMR and the benefits of rapid AST in our conversations with distributors from around the world who are reaching out to Q-linea to explore the potential for ASTar in their home markets. Our team is working with a selection of partners to plan our continued geographic expansion. We are conscious of the need to maintain a high standard of customer service experience as we grow, which can be an extra challenge in markets beyond Europe and North America. This is an area of particular focus for us as we bring ASTar to patients globally.

Maintaining market leadership
Even while managing the final stages of our restructuring process this quarter, the R&D team continued to hit key milestones in our priority development projects. These will bring further menu expansions to the ASTar platform along with continued operational improvements to the instrument itself. Our development pipeline aims to ensure that ASTar remains the field leader in technical and clinical performance and overall workflow efficiency and ease-of-use.

In conclusion, it has been another quarter with a high pace of activity on multiple fronts. I must extend my appreciation to the whole of the Q-linea team who are making great progress towards our shared mission. We are a relatively small company but are taking bold steps to shape the global response to the urgent burden of sepsis and antimicrobial resistance.

Uppsala, 10 July 2024, Stuart Gander, CEO

The report has been prepared in a Swedish original and an English translation. In the event of any discrepancies between the two, the Swedish version is to apply. This report has not been reviewed by the auditor of the Company.

Presentation
Q-linea invites investors, analysts and the media to an audiocast and teleconference (in English) today, 11 July 2024, at 1:00 to 2:00 p.m. (CEST). CEO Stuart Gander and CFO Christer Samuelsson will present Q-linea, comment on the interim report for the January to June 2024 period and respond to questions.
To participate via webcast, please visit the following link: https://ir.financialhearings.com/q-linea-q2-report-2024
There will be an opportunity to ask questions in writing at the webcast.

If you would like to ask questions verbally via conference call, please register at the following link: https://conference.financialhearings.com/teleconference/?id=50048292

You will receive a telephone number and a meeting ID to log into the conference call after registering. There will be an opportunity to ask questions verbally during the conference call.

For more information, please contact:

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About Q-linea

Q-linea's rapid AST system, ASTar®, accelerates and simplifies the time-sensitive workflows faced during the treatment of patients with bloodstream infections and sepsis. Hospitals use ASTar to vastly reduce the time to optimal antimicrobial therapies and ensure that patients receive the correct treatments sooner — when time matters most. We are helping to create sustainable healthcare, now and in the future, and safeguard the effectiveness of antibiotics for generations to come.
Q-linea is headquartered in Uppsala, Sweden and has regional offices in Italy and the USA, with partnerships worldwide.
ASTar Instrument and ASTar BC G- Consumable kit are CE-IVD marked and FDA 510(k) cleared. For more information, please visit www.qlinea.com

This information is information that Q-linea is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-07-11 07:30 CEST.

Attachments

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