

Interim report 1 January - 30 September 2024

Growing pipeline in the US

Third quarter: 1 July - 30 September 2024

- Net sales amounted to SEK 0.6 million (3.0).
- The operating result totalled SEK -41.1 million (-48.2).
- The result for the period amounted to SEK -42.4 million (-48.6).
- Earnings per share before and after dilution amounted to SEK -0.36 (-0.56) SEK.
- Cash flow from operating activities totalled SEK -50.0 million (-54.5).

Period: 1 January - 30 September 2024

- Net sales amounted to SEK 2.2 million (4.4).
- The operating result totalled SEK -162.4 million (-175.1).
- The result for the period amounted to SEK -164.0 million (-175.1).
- Earnings per share before and after dilution amounted to SEK -1.4 (-3.59).
- Cash flow from operating activities totalled SEK -142.1 million (-180.3).
- As of 30 September 2024, the Company had a total of SEK 7.5 million (81.9) in available funds. In addition, the Company has an unutilized loan facility of SEK 23 million (41.5) from the principal owner Nexttobe.

Significant events

In the third quarter of 2023

- The Company participates in its first public tender in Belgium.
- Two American hospitals presented ASTar-data in line with good results shown in several European studies
- CMS grants New Technology Add-on Payment (NTAP) for ASTar with a reimbursement of USD 97.50 per eligeble patient.
- Q-linea expands its operation to Romania and the Middle East through two new distribution agreements.

After the of the period

- Q-linea announces changes in executive leadership team and expands US commercial team.
- Large US reference laboratory completes ASTar evaluation successfully.
- Two UK commercial evaluations successfully completed.
- The Company receives a formal request for a contract from a prominent hospital in Milano and participates in a multi-site public tender in Italy.
- First clinical evaluation of ASTar begins at a National Cancer Institute-designated (NCI) cancer center
- Q-linea resolves to carry out a rights issue of approximately SEK 225 million and enters into an agreement for a bridge loan facility of approximately SEK 40 million.



CEO comment

ASTar® awarded NTAP funding

\$97.50 in reimbursement for Medicare and Medicaid patients

Unique reimbursement from Medicare for ASTar analyses! Q-linea is the only company to receive NTAP reimbursement from Medicare for rapid resistance testing. We estimate that this will accelerate the use of ASTar in the U.S.

More than 66 million people in the United States are covered by the Medicare health insurance. It is partly publicly funded, partly paid by the patient.

In August, the U.S. Centers for Medicare and Medicaid Services (CMS) announced that ASTar System had been awarded NTAP funding. NTAP is an abbreviation of New Technology Add-on Payment. It is a way to make it easier for hospitals to introduce new technologies into clinical routines. ASTar qualified by meeting criteria around significant clinical improvement, novelty and cost.

The funding is valid for three years, from October 2024 to September 2027. Patient cases involving the use of ASTar and eligible for reimbursement will be identified using a unique NTAP code. The additional reimbursement to the hospital will be \$97.50 per eligible Medicare patient.

Growing pipeline in the US

Even before the FDA approval in April, we started a number of ASTar evaluations and it is gratifying to see the results. In August, clinical data was presented for the first time by a U.S. university hospital at the annual meeting of the Southwestern Association of Clinical Microbiology. The performance and results were as expected and in line with what had previously been shown in several European studies. At a webinar in September, Penn State Hersey Medical Center and George Washington University presented additional interim data from their respective studies, corroborating the August presentation.

This US-specific clinical data is an additional factor driving the growing pipeline of customers seeking to evaluate the ASTar platform. Our US team has been focused on the top 200 – 300 hospitals and labs in the US, and now have a sizeable pipeline of customers lined up for evaluations through the autumn and winter. Several of these are at or nearing completion and are entering commercial contracting. I hope to be able to announce our first US commercial placements during Q4 2024.

Market expansion

We continue the geographical expansion with a focus on countries and regions that are actively working to address the challenge of antibiotic resistance. Romania is one of the countries with the highest number of infections with antibiotic-resistant bacteria in the EU. With the help of financial support, the country has drawn up a national action plan for optimising the use of antibiotics. We have found a very knowledgeable and experienced partner in S.C. Mecro System S.R.L. to bring ASTar into the country.

After evaluation of several potential partners for expansion in the Middle East, we are very pleased to have entered into an exclusive agreement with the medical technology company AMICO Group. The company is active in 12 countries in the Middle East and North Africa and employs more than 1,300 people. Q-linea will benefit from their extensive experience in clinical microbiology.

In our other core EMEA markets, projects continue to move through the pipeline. Our partner in the UK, ProLab, has completed two successful evaluations with others ongoing. We anticipate that these will convert to commercial systems, along with similar projects in Benelux and Italy which should yield contracts in Q4.



Organization and cost savings

The previously communicated cost savings program is now clearly visible in the results for the third quarter. In addition to the total cost savings of approximately SEK 50 million on an annual basis, there has also been a shift of resources and focus from development and clinical studies to sales and market support activities. We will continue to maintain good cost control and to balance the increased need for in-market resources with savings in other areas.

As Thomas Fritz and Tiziana Di Martino prepare to leave the management team, having both been instrumental in establishing ASTar on the market, Franco Pellegrini, who led our launch in the Italian market, will take on the overall leadership of the EMEA commercial and clinical teams. We have also strengthened our US commercial team to meet the demands of a fast-expanding pipeline.

Financing

We are entering a critical phase of Q-linea's journey, having positioned ourselves assertively during 2024 for accelerated commercial growth. The communicated Rights Issue will provide us with funding for a pivotal upcoming period when we expect to see a steady pace of commercial contracts and revenue generation.

Uppsala, den 4 November 2024, Stuart Gander, koncernchef

This report has been reviewed by the auditor of the Company. 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.

Presentation

Q-linea invites investors, analysts and the media to an audiocast and teleconference (in English) today, 5 November 2024 kl. 13:00 – 14:00 (CET). CEO Stuart Gander and CFO Christer Samuelsson will present Q-linea, comment on the interim report for the January to September 2024 period and respond to questions.

To participate via webcast, please visit the following link: https://ir.financialhearings.com/q-linea-q3-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=50048764

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. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-11-05 07:30 CET.

Attachments

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