

## INTERIM REPORT 1 JANUARY – 30 SEPTEMBER 2019

### A quarter of intense preparation

#### Third quarter, 1 July - 30 September 2019

- Net sales amounted to SEK 0.0 million (0.3).
- The operating result totalled SEK -35.8 million (-28.8).
- The result for the period amounted to SEK -35.1 million (-29.3).
- Earnings per share before and after dilution amounted to SEK -1.53 (-1.98).
- Cash flow from operating activities totalled SEK -35.8 million (-31.2).

#### Period, 1 January - 30 September 2019

- Net sales amounted to SEK 1.0 million (0.8).
- The operating result totalled SEK -117.1 million (-88.4).
- The result for the period amounted to SEK -115.4 million (-88.9).
- Earnings per share before and after dilution amounted to SEK -5.04 (-6.46).
- Cash flow from operating activities totalled SEK -117.7 million (-85.3).
- At 30 September 2019, cash and cash equivalents amounted to SEK 19.2 million (354.4), short-term investments in fixed-income funds to SEK 211.2 million (150.0) and investments in listed bonds to SEK 151.7 million (0).

#### Significant events

##### *in the third quarter of 2019*

- The management team was strengthened with MD Tiziana di Martino who was appointed Chief Medical Officer and Thomas Fritz who was appointed Chief Commercial Officer.
- The company issued 117,424 new shares in order to ensure delivery of performance shares under the long-term incentive programme (LTIP 2019).

##### *after the end of the period*

- The start date for the company's clinical studies was postponed from the first quarter to the second half of 2020.
- Q-linea received a positive response from the US Food and Drug Administration (FDA) regarding the design of the company's planned study in the US.

## Comments by the CEO

### **A quarter of intense preparation**

We worked simultaneously across many fronts in the third quarter to continue to build a strong platform for future launches. For example, we strengthened the commercial organisation, started to anchor our health economics studies, attended major trade fairs, had a positive follow-up meeting with the FDA on our study plan, made preparations for our regulatory studies and, last but not least, held intensified discussions with potential partners.

A large and important element of this work was strengthening the commercial organisation. We recruited a highly experienced Chief Commercial Officer, Thomas Fritz, who in previous roles has successfully driven results in both mature and emerging markets. He has already proven himself a major asset ahead of our launches in Europe and the US. At the start of the year we also employed an equally experienced Chief Medical Officer, Tiziana Di Martino (MD, MSc, MBA), who has already conducted several in-depth interviews with clinics and doctors to help us gain even better understanding of our market. The feedback we have received to date has been incredibly positive, particularly on our comprehensive antibiotics panel. This feedback has come not only from the laboratory managers we work with, but also from administering physicians.

We have now started to anchor our health economics studies with the clinical laboratories that we are in contact with and we will soon choose the laboratories that we want to work with. We intend to start the first health economics study in the second half of 2020. Our preparations for the clinical study are proceeding according to plan and we have now obtained all the isolates that we need.

The positive feedback we have received also came from the trade fairs we visited during the quarter. We attended IDWeek in Washington and the Annual Meeting of the American Association of Clinical Chemistry (AACC) in California. We did not exhibit at these events but participated as visitors. I believe that awareness of Q-linea is relatively high, with particularly high curiosity about our broad offering. Many see that the capacity and potential of our ASTar® system is significantly higher than what is currently found in the market. In mid-November we will exhibit at the FIS, Federation of Infection Societies Conference, in Edinburgh, which was especially interesting since the UK is far advanced in terms of infection diagnostics and antimicrobial resistance.

We have mostly received highly positive feedback regarding ASTar, particularly from the in-depth interviews we conducted both in Europe and the US. We have also learnt that clinics and physicians want to see Meropenem-Vaborbactam (MER-VAB) included in our antibiotics panel. This would provide more comprehensive analytical results for patients with resistant bacterial infections. Greater resistance to antibiotics has meant that combination therapies have become increasingly common and important for treating patients with resistant bacterial infections. The added value provided by MER-VAB is therefore considered substantial, which is why we are now taking measures to include it in our antibiotics panel.

Discussions with potential sales partners intensified considerably during the quarter. We are holding discussions with the most interesting companies in the market and, as promised, I am looking forward to presenting an agreement with future sales partners at the end of the year. Interest in ASTar is widespread since the system stands out from all other systems. Isolates, semi-automatic systems or high value – no matter which it is, ASTar can address all these factors with accurate MIC values. No other product can do this. The capacity of our system is unique and our reference samples are of the highest class.

For a couple of months we have had three alpha systems operational, essentially 24 hours a day, seven days a week. The ASTar system has, quite simply, been thoroughly tested. Overall, the results have been positive, but an important component that we purchase from a third-party manufacturer has shown errors at a higher rate than we deem acceptable. The reliability of the component needs to be improved and we have postponed our schedule so as to jointly solve the issue together with the supplier.

We do not believe this affects the positive discussions we have with our potential future sales partners. Furthermore, we do not see that it affects the CE marking of the system. However, it does mean that our clinical studies in the US and Europe are expected to begin in the second half of 2020 instead of the first quarter of 2020 as previously anticipated. ASTar will be presented at ECCMID in Paris. This is a more traditional launch strategy with a longer test period of ASTar before commercial launch.

After the end of the quarter, we also received a highly positive response from the FDA regarding our proposed clinical study in the US, allowing Q-linea to perform parts of the study itself based on the high educational level of our clinical microbiologists. The FDA's proposal to change the design of the quality control process during the study could also result in a shorter development period for our planned product for semi-automatic isolate analysis, which is naturally also very positive.

Of course, it feels disappointing to postpone our clinical studies and the launch of ASTar, but overall the quarter has been positive and the feedback from the FDA was highly gratifying. We have taken many important steps to make ASTar ready for approval and launch to market. The feedback we are receiving both from potential customers and in discussions with possible partners is very positive and fills us with enthusiasm. I look forward towards the journey ahead together with you all.

Uppsala, November 2019

Jonas Jarvius, President

*This 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, 7 November, at 1:00 to 2:00 p.m. (CET). President Jonas Jarvius and CFO Anders Lundin will present Q-linea, comment on the interim report for the January to September 2019 period and respond to questions.

Webcast: <https://tv.streamfabriken.com/q-linea-q3-2019>

Telephone number for the teleconference: SE: +46856642705 UK: +443333009262 US:+18338230586

## Upcoming reporting dates

13 February 2020	Year-end report, Q4	January to December 2019
Week of 13 April 2020	Annual Report 2019	January to December 2019
7 May 2020	Interim report, Q1	January to March 2020
26 May 2020	Annual General Meeting	
16 July 2020	Interim report, Q2	January to June 2020
5 November 2020	Interim report, Q3	January to September 2020

## About the company

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*This information is information that Q-linea AB 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, on 7 November 2019 at 7:30 a.m. (CET).*

## About Q-linea

Q-linea is an innovative research, development and manufacturing company that primarily develops instruments and disposables for rapid and reliable infection diagnostics. Q-linea's vision is to help save lives by ensuring antibiotics continue to be an effective treatment for future generations. Q-linea develops and delivers preferred solutions for healthcare providers, enabling them to accurately diagnose and treat infectious disease in the shortest possible time. The company's lead product ASTar™ is a fully automated instrument for antibiotic susceptibility testing (AST), giving a susceptibility profile within six hours directly from a positive blood culture. For more information, please visit [www.qlinea.com](http://www.qlinea.com).