

Strengthened financial position and good growth for the OEM business

I am pleased that we were able to deliver milestones during the fourth quarter, both in the development of the new product platform and in our quality work.

Sales for the fourth quarter increased by six percent compared to the previous year, totaling SEK 149 million. Organically, sales fell by eight percent. Sales of consumables continue to take a positive direction. The use of instruments is back to pre-pandemic levels. We had lower sales of 3-part instruments, which is partly explained by a shift from 3-part to 5-part instruments. However, I believe that 3-part instruments will continue to be used in the decentralized market and will make up the majority of the installed base for many years to come. Weak local currencies are currently reducing the scope for investment, especially in developing countries. Several countries have also had restrictions imposed by central banks on payments in foreign currency. The OEM and CDS brand business continued to show good growth, with fourth quarter sales up 49 percent and full-year growth of 33 percent.

In mid-2022, Fuji began selling veterinary products in three countries in southern Europe. We have received positive feedback from the first installations and we are now discussing an extended distributor-agreement.

Strengthened gross margin

The gross margin in the fourth quarter was 44.7 percent, which is 3.5 percentage points better than last year and 4.0 percentage points better than the third quarter of 2022. This was due to greater penetration of price increases and to a favorable product mix with a higher share of consumables. In the fourth quarter, gross margin and earnings were again affected by high component costs and purchases at spot prices, as well as a negative currency effect. Purchases at spot prices negatively impacted the gross margin by about three percentage points. Operating profit totaled SEK 10 million, and the operating margin 6.7 percent.

Cash flow from operating activities in the fourth quarter totaled SEK 13 million, which is approximately SEK 1 million better than in the previous year. As previously communicated, we are continuing to bring forward some material purchases and are building buffer stocks of critical components to ensure supply. As a result, we have increased inventories by SEK 4 million.

First formal release of our new product platform

Intensive work is underway to finalize the prototypes to be used for clinical trials and study implementation in 2023. These study results will be used for regulatory filings for the first product, a 5-part instrument, for which filing is planned for the end of this year. At the end of last year, we passed an important development milestone with the first technical release of our cloud solution. By putting this infrastructure in place, we can acquire experience in the operation and use of this type of service ahead of the full commercial launch in 2024.

Investments in the new product platform totaled SEK 15 million for the quarter.

Key milestones in quality work

Over the past year we have invested a lot of time and effort in the implementation of the IVDR, the new European regulatory framework, and in improving our quality systems. Clear proof of our dedicated quality work is that in November we obtained the CE mark according to IVDR for our 3-part instruments. Only a small number of companies in Europe have obtained new ISO13485 certificates and CE marks under the IVDR.

The US Food and Drug Administration (FDA) conducted an inspection of our Swedish operations in November. The observations noted by the FDA have been corrected. Our US subsidiary, CDS, is in the process of addressing the observations noted by the FDA in the summer.

With the IVDR certification completed, we are well prepared for future regulatory submissions for new products.

Improvements in production to support growth

One key growth initiative generating increased revenues is our OEM business, where we saw strong growth during the quarter. In the autumn, we invested in our US production to increase capacity for our OEM customers and to prepare for the manufacture of reagents for our upcoming product platform.

Establishment of local licensed production of hematology reagents in India with our partner Q-Line Biotech is progressing according to plan. We continue to expect customer deliveries in India to start in the third quarter of 2023.

Adaptation to new market conditions

To address the macroeconomic challenges of rising costs and the tougher market environment, Boule will also make cost savings in the first quarter of 2023. We are conducting a review of our operations to identify areas that can be streamlined to compensate for inflation-driven higher cost levels. We are simplifying and streamlining the organization. This includes adjusting staffing levels, both employees and consultants, which will reduce running costs going forward. The savings will result in one-off costs that will be recognized in the first quarter of 2023.

We completed a rights issue of SEK 150 million, which will be used to complete the development of the new product platform. It was gratifying to see that the rights issue was significantly oversubscribed.

Finally, I would like to extend my warmest thanks to all distributors, suppliers and employees for their fantastic efforts in a very challenging 2022. It is difficult to predict what geopolitical and macroeconomic challenges may lie ahead. Thanks to the support of our shareholders, the rights issue has strengthened our financial position and, together with the savings and efficiency improvements we are now making, we are well equipped to meet the challenges of the world around us.



Jesper Söderqvist
CEO and Group President

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