

BiBBInstruments AB

Exercise period T01 22 May–5 June 2025

CEO letter

MARKETING

Dear shareholder,

This spring, BiBB has taken several important steps towards commercialization, despite an environment characterized by economic and geopolitical uncertainty, growing protectionism and increased trade tariffs. In connection with our current warrant program, where you, as a warrant holder, have the opportunity to subscribe for new shares in BiBB during the period May 22–June 5, 2025, I would like to share some of the milestones achieved and what we can look forward to in the second half of the year – an exciting period to say the least.

We will remember 2025 as the year when we began our journey from a development-stage company to a commercial company. The year began with the first commercial customer order for EndoDrill® GI, when UC Davis Health in California purchased a series of biopsy instruments after a thorough evaluation last year, led by Dr. Antonio Mendoza Ladd, Medical Director of Endoscopy.

Dr. Mendoza Ladd has also rapidly generated clinical data published in scientific journals. A clinical case study of eight patients showed – similar to the results from the Swedish pilot study – 100% diagnostic accuracy after only a single needle pass in tumors located in organs such as the pancreas, esophagus, stomach and small intestine. In parallel, Dr. Mendoza Ladd has coordinated a retrospective multicenter study of 28 patients at five university hospitals in Europe and the USA. Biopsy samples were taken from tumor lesions, mainly in the pancreas, retroperitoneum, and stomach. A summary of this “real world” study was published in March, and the authors concluded that EndoDrill® GI is both safe and effective. The results were presented orally in early April at ESGE Days in Barcelona.

The importance of convincing clinical data cannot be overstated. The fact that a single needle puncture (“one pass”) with EndoDrill® GI is sufficient in the vast majority of patient cases is a strong selling point, especially since international guidelines recommend 2-5 needle passes with existing, manually handled needle instruments. The high sample quality after only “one pass” is an example of an important competitive advantage that will be highlighted in the second half of 2025, when our new partner, TaeWoong Medical USA, begins the launch of EndoDrill® GI in the USA. This is a major step forward for BiBB and we are very pleased to have recently signed a Letter of Intent (LOI) for distribution with TaeWoong – a perfect partner in the USA for BiBB. TaeWoong is a fast-growing distributor with an innovative portfolio of therapeutic endoscopic ultrasound products, where EndoDrill® GI serves as a natural complement in diagnostic sampling. We will soon finalize the distribution agreement and focus on training efforts for TaeWoong’s sales force to enable a successful launch in the important US market. Initially, sales efforts will target selected hospitals in the fall of 2025, followed by a broader launch next year.

On May 15, we received a very timely announcement – given the recent LOI with TaeWoong – from the United States Patent and Trademark Office (USPTO) stating their intent to approve our first patent application for the EndoDrill® technology within the first of three patent families. Having a granted patent when we start the launch in the US is of great importance and strengthens our position.

In parallel with our activities in the US, we are evaluating potential European distributors who have shown interest in selling EndoDrill® in Europe. We have made considerable progress in discussions with promising partners and plan to sign an agreement with a suitable partner towards the end of the year – when the most resource-intensive launch activities in the US are expected to be completed. This will enable the start of sales in Europe in 2026. At the same time, we look forward to launching our next product, EndoDrill® EBUS, for ultrasound-guided sampling of the lungs – an area experiencing rapidly growing clinical demand.

A prerequisite for commercial success is that we can produce EndoDrill® GI in larger volumes. Therefore, in 2025, we are transferring the production of single-use instruments to a well-reputed and experienced contract manufacturer in Sweden. The project is progressing according to plan, with the zero series scheduled for the summer, while series production will begin in the autumn. To further strengthen our team for the commercial phase, we have also recruited three key professionals in research & development, medical affairs and logistics.

In addition, over the past few months, EndoDrill® GI has been successfully introduced at three new university hospitals in Münster (Germany), Porto (Portugal) and Detroit (USA). These clinical activities also included sampling for the new indication liver biopsy. Another highlight was a successful live patient demonstration in Porto during an endoscopy congress. EndoDrill® GI is currently being evaluated in about ten hospitals in the US and Europe, and over the next six months we will primarily focus on introducing the product to new hospitals in the US, in collaboration with TaeWoong.

With the world’s first market-cleared powered biopsy instrument for endoscopy, we are taking a leading position in the fastest growing endoscopic segment. EndoDrill® products are developed to offer physicians with more precise and effective biopsy instruments – and to provide patients with faster, safer diagnoses and earlier treatment initiation. In 2025, we will take important steps to establish EndoDrill® as a new standard in ultrasound-guided endoscopic sampling. Our strategy going forward is built on three pillars: strong distribution partners, scalable production and continued clinical evidence.

If you do not hold any warrants or want to buy more, they will be traded on Spotlight Stock Market until June 3, 2025. Please remember to notify your bank or custodian to exercise the warrants for subscription of shares by June 5. Please note that some banks may require an earlier response from their clients, so look up in good time what date that applies to your specific custodian. One warrant gives the right to subscribe for one new share for SEK 3.25, and BiBB will mainly use the capital raised to finance the market launch next year.

I look forward to continuing this journey with you, our investors and partners. With our groundbreaking, patented technology and a strong and dedicated team, we are well equipped to make a real difference in the future of cancer diagnostics.

BiBB
INSTRUMENTS

Best regards,
Fredrik Lindblad, CEO