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SENZIME AB (PUBL)

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COMPANY OVERVIEW

Introduction

Senzime AB (publ), corp.reg no 556565–5734 ("Senzime" or the "Company"), develops and markets CE-marked and FDA-approved medical device systems, driven by algorithms and disposable sensors that assess the patient's muscle function before, during and after surgery under anesthesia, as well as systems for monitoring respiratory function and other vital functions. The Company's goal is to help improve clinical precision and simplify medical care. One of Senzime's systems is TetraGraph®, which continuously monitors the degree of neuromuscular blockade digitally to prevent complications. Fewer complications lead to higher patient satisfaction, shorter hospital stays and lower healthcare costs. With a usability focus, the Company's vision is that TetraGraph® will be used in all surgery where muscle relaxant drugs are used, to ensure a safe awakening for all patients.

The ExSpiron® system monitors patients' respiratory volume and respiratory rate in real time and is a non-invasive monitoring system for respiratory volume and minute ventilation for both inpatients and outpatients. Sales of ExSpiron® are based on a "razor and razorblade" business model, driven by an installed base of monitors with recurring sales of disposable sensors.

Senzime's product portfolio also includes innovative, patient-centric solutions that enable automated and continuous monitoring of biological substances such as glucose and lactate in blood and tissue fluid – CliniSenz® Analyzer and OnZurf® Probe.

The Company's share is traded on Nasdaq Stockholm. The object of the Company is set out in Section 3 of the Articles of Association.

History

Senzime was founded in 1999 with the mission to develop patient-centric systems for measuring life-critical substances. The Company was originally set up as a shelf company under the name of Aktiebolaget Grundstenen 83501. The name of the Company was changed to Point of Care AB in 1999, and to Senzime Point of Care AB in 2001. The Company's current name was registered with the Companies Registration Office on 3 April 2008.

In 2001, members of the Crafoord family, represented by Adam Dahlberg, invested in the Company. During 2004, Senzime completed a first prototype for clinical blood glucose monitoring for healthcare. In 2008, Senzime was listed on Spotlight Stock Market (then Aktietorget) and in the years that followed, the Company was granted important in the US market among others for continuous monitoring of glucose, lactate and other metabolites.

In 2010, Senzime initiated a clinical trial together with Uppsala University Hospital. The trial was a step to continue building on the Company's clinical data in the field of continuous and automated blood glucose monitoring in intensive care.

Senzime has conducted initiatives within biotechnology, which contributed with knowledge and validated the technology platform. The Company entered into an agreement with Dutch company Applikon Biotechnology for the commercialisation of continuous monitoring in drug manufacturing processes. However, Senzime decided to shift the main focus of its business operations to health and medical care, and to discontinue further investments in biotechnology.

MD Biomedical AB, Corp. Reg. No. 556837–0273, was acquired by the Company in 2015. MD Biomedical AB was founded in 2011 and has developed and patented OnZurf® Probe, a new generation of micro-dialysis catheters. Senzime's products, CliniSenz® Analyzer and OnZurf® Probe, enable the detection of post-operative complications much earlier than conventional methods and can therefore help to improve patient safety and reduce healthcare costs.

In spring 2016, the Dutch medical devices company Acacia Designs B.V. was acquired, in line with the Company's strategy to build a world-leading patient monitoring company. Acacia Designs B.V. was founded in 2014,

based on more than 20 years of research under the supervision of Professor Sorin J. Brull, an anesthesiologist and world authority in the field, and Dr David Hampton with in-depth experience as a Director from Medtronic Inc. The acquisition therefore broadened the Company's activities to also include solutions for patient monitoring during anesthesia. OnZurf® Probe was out-licenced for the European market in 2020 and the TetraGraph® system is today main focus of Senzime's business. The TetraGraph® system makes it possible to determine the correct drug dosage and make a quantitative assessment of when it is safe to awaken the patient and allow spontaneous breathing.

In 2017, Senzime's share was transferred from Spotlight Stock Market to Nasdaq First North Growth Market. In 2018, a targeted launch to key European markets commenced following the CE approval of TetraGraph® in December 2017. In autumn 2019, Senzime was granted approval from the United States Food and Drug Administration (FDA), which means that the Company can market and sell TetraGraph® in the US. The Company also received regulatory approval in Japan and South Korea in the same year.

In January 2020, the US subsidiary Senzime Inc. was registered in Florida and the subsidiary has since strengthened its organisation with several sales representatives.

In the first quarter of 2021, the Senzime GmbH subsidiary was also established in Germany, the largest medical device market in Europe.

In June 2021, Senzime's share was transferred from Nasdaq First North Growth Market to Nasdaq Stockholm. In the fourth quarter of 2021, Senzime inaugurated its production facility for the manufacture of TetraGraph® in Uppsala, Sweden, and the Company's products, quality management system and production simultaneously received certification in accordance with the European Medical Device Regulation 2017/745.

In the first quarter of 2022, the TetraGraph® system was approved for use in small children in the European Union's internal market via CE marking of the TetraSens® Pediatric sensor. In the first quarter 2022, the Company also submitted an application to the FDA to market TetraSens® Pediatric in the US.

On 21 June 2022, Senzime announced that the Company had signed a strategic license and connectivity agreement with the US company Masimo. The agreement and collaboration are described in more detail in the full prospectus, under the sections "*Partnerships and collaborations*" and "*Significant Agreements*".

In July 2022, the US medical device company Respiratory Motion, Inc. ("RMI") was acquired. The acquisition is in line with the Company's strategy to build a world-leading patient monitoring company. RMI was founded in the US state of Delaware in 2011 and is based in Watertown, Massachusetts. RMI has developed ExSpiron®, a unique non-invasive monitoring solution for minute ventilation.

Vision

Senzime's vision is a world without anesthesia and respiratory-related complications. The Company's mission is to develop high-technology digital solutions to help save lives, optimise patient outcomes, reduce complications, and reduce healthcare costs related to surgical procedures.

Operational objectives and challenges

Senzime aims to be a market leader with the TetraGraph® system for neuromuscular monitoring by improving clinical precision and simplifying medical care, and with the ExSpiron® system for non-invasive minute ventilation monitoring. By preventing complications and enabling healthcare professionals to follow guidelines and drug recommendations, TetraGraph® and ExSpiron® are helping to shorten hospital stays, reduce healthcare costs, and improve patient outcomes.

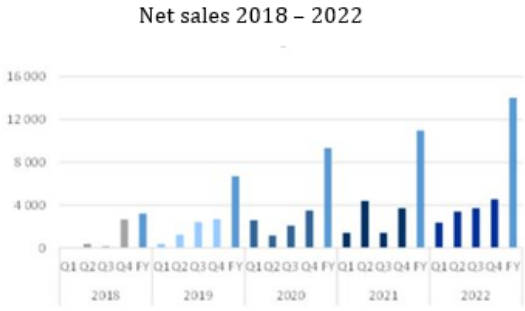
Senzime's long-term objective is to be a market leader in neuromuscular monitoring and minute ventilation monitoring, with a market share of more than 10 per cent.

The Company is focused on a higher placement of monitors in hospitals through a so called Consignment business model. The Consignment business model means that monitors are placed in a hospital, and the hospital signs a contract to borrow or use the monitors, but is required to purchase the

related disposable sensors. The sale of disposable sensors is the leverage on which Senzime's business model is based. The Company will also broaden its product and service offering to meet the hospitals' varying needs.

Net Sales over time

The graph below provides an overview of how the Company's net sales have developed over the years 2018–2022 (SEK thousand).



Financial targets

On the date of this Prospectus, the Company's financial targets are to achieve sales of SEK 275–325 million by 2025, have a long-term EBITDA margin exceeding 40 per cent, and a market share of at least 10 per cent in the Company's active market segments. The latest announcement of financial targets was at the Company's investor event with related press releases on 15 November 2022.

The Company's financial targets for 2025 have not been examined or reviewed by auditors. For the financial targets, Senzime has not prepared any pro-forma financial statements, or published any additional financial information other than the Company's financial reports.

Underlying assessments and assumptions for the financial targets.

Senzime expects continued strong sales development of the TetraGraph® system and the sensor TetraSens® in the US. The Company expects the existing customer base as well as new customers added during 2022, to increase their use of the sensor during the year. Customers who have recently installed monitors are expected to start generating sales of the sensor in 2023.

ExSpiron® has recently been fully integrated into Senzime's organisation and the sales representatives have started approaching new customers. Senzime expects that several customers using the ExSpiron® x1 will upgrade to the x2 monitor, which will contribute positively to sales.

In the US and Europe, Senzime is currently participating in several procurement processes in the five largest markets as well as the Nordic region. The Company expects some of the processes to turn out well and may start to contribute positively to sales in 2023.

ExSpiron® has been introduced in Germany as well as in a selection of markets via distributors. The response has been positive and sales of systems and sensors are expected to increase during the course of the year.

Factors that lie within Senzime's control or ability to influence:

1) That the implementation of ongoing projects, primarily evaluations in hospitals, continues as planned for 2023.

2) That the Group's cost control and development remain in line with Group Management's expectations for the 2023 financial year.

Factors that lie beyond Senzime's control or ability to influence:

1) That there are no significant changes in macroeconomic factors that could affect Senzime or the Company's existing customers.

2) That there are no significant changes concerning public sector investments in healthcare in the Nordic region and other European countries.

3) That there are no significant changes in currency exchange rates. Senzime is exposed

to exchange-rate risk because of the Company's global business activities.

Product portfolio

TetraGraph®

TetraGraph® is a CE-marked and FDA-approved, innovative, and user-friendly digital system for monitoring patients undergoing anesthesia with muscle relaxant drugs. TetraGraph® is designed to measure the effects of muscle relaxant drugs simply and accurately, which helps the surgeon assess the degree of neuromuscular function in real time and therefore, when it is safe to awaken the patient after surgery. The system consists of a portable, hand-held patient monitoring device and disposable sensors.

By preventing complications and enabling healthcare professionals to follow guidelines and drug recommendations, TetraGraph® is contributing to shorten hospital stays and reduce healthcare costs. The international market potential for TetraGraph® is approximately 166,000 operating theatres which, combined, perform approximately 79 million surgical procedures annually.[1]

Since the fourth quarter of 2021, TetraGraph® has been manufactured in the Company's own premises in Uppsala, Sweden.

TetraSens®

The TetraSens® electrode is CE-marked and FDA-approved and used together with TetraGraph®. It consists of two stimulation electrodes – one recording electrode and one distal reference electrode. TetraSens® is designed for single use to avoid cross-contamination between patients and application is quick and easy. The electrodes can be attached to either hand with the stimulation electrodes on the forearm over the ulnar nerve, and the recording electrode from either the hypothenar muscles below the little finger (*m. abductor digiti minimi)*, from the thenar muscles below the thumb *(m. adductor pollicis)* or the first dorsal interosseous muscle *(m. first dorsal interosseus).* The electrodes can also be used on either foot with the stimulation electrodes on the posterior tibial nerve and the recording electrode on the flexor hallucis brevis *(m. flexor hallucis).*

TetraSens® Pediatric

TetraSens® Pediatric has been specially designed for infants and children (from 4 weeks old) and is used together with TetraGraph®. Like TetraSens®, it consists of two stimulation electrodes – one recording electrode and one distal reference electrode – but is made from transparent and flexible material, making it easier to position the electrodes correctly over nerves and muscles in small children. The electrodes can be attached to either hand with the stimulation electrodes over the ulnar nerve closest to the wrist, and the recording electrode from either

[1] For more detailed references and estimates, refer to footnote 3 above.

the hypothenar muscles below the little finger (m. abductor digiti minimi) or from the thenar muscles below the thumb (m. adductor pollicis). TetraSens® Pediatric is CE-marked and the Company submitted an application to the FDA for the product in the first quarter of 2022.

ExSpiron®

ExSpiron® is a non-invasive monitoring system for respiratory volume and minute ventilation in both inpatients and outpatients.

Minute ventilation is the volume of air that a person breathes per minute and is measured in litres per minute. A change in minute ventilation is one of the first indications of respiratory deterioration. Reliable and non-invasive methods for monitoring respiratory function changes in patients are limited.

ExSpiron® enables patient-centric, non-invasive respiratory volume monitoring, which has been shown to provide one of the first indications of changes in respiratory function.

TetraConnect

TetraConnect is a cloud-based platform that makes it easy to view and export data from TetraGraph® in both PDF and Excel formats. The online portal also provides the user access to comprehensive data records for clinical use or research purposes. It is also possible to select events, make notes and see the neuromuscular response measured during surgery on detailed graphs.

TetraGraph® Philips Interface

Data from the TetraGraph® monitor can be transferred to selected patient monitoring systems. The neuromuscular transmission data will be integrated into existing infrastructure, allowing the uploading of patient data into a local electronic medical record ("EMR").

TetraGraph® Philips Interface enables transfer of neuromuscular parameters to Philips patient monitors, from where it can be viewed on a Philips IntelliVue monitor.

OnZurf® Probe

OnZurf® Probe is a CE-marked product based on micro-dialysis technology that enables continuous sampling from individual organs such as the oesophagus, stomach and liver. OnZurf® Probe is a unique micro-dialysis catheter for clinical use, and placed on the surface of the organ without penetrating the tissue surface and causing unnecessary organ stress.

In 2020, Senzime signed a license agreement for OnZurf® Probe with the Italian company Moss S.p.A. The agreement gives the licensee, Moss S.p.A., a ten-year manufacturing and sales right to OnZurf® Probe in Europe. Under

the license agreement, Senzime retains the patent rights and the right to commercialise OnZurf® Probe in all markets outside Europe.

CliniSenz® Analyzer

CliniSenz® Analyzer is the system of the future for post-operative and continuous patient monitoring in hospital environments. The system requires only small sample volumes for analysis, and the results from CliniSenz® Analyzer are specific and highly accurate. The Analyzer utilises enzyme-based heat flows, which reduces the risk of interference from other compounds such as pharmaceuticals.

CliniSenz® Analyzer is used together with OnZurf® Probe and other micro-dialysis catheters. CliniSenz® Analyzer is currently under development and prototypes of CliniSenz® Analyzer have been produced and used clinically in studies at Uppsala University Hospital. However, due to Senzime's current focus on TetraGraph®, the Company is not working actively with this project.

Project overview

Senzime develops medical devices, which means that the Company's product development is "risk-based", with a focus on safety, efficacy and usability, as well as regulatory compliance.

Depending on the project, the Company applies either the waterfall model, where all phases of a project flow like a waterfall or more agile practices when several alternative methods need to be evaluated fast.

Partnerships and collaborations

Senzime uses a large number of distributors in Europe, Asia and the US. The distributors serve a key role as the Company's extended sales force, and the Company therefore works closely with its distributors in terms of both training and customer support activities. This ranges from direct support during clinical evaluations and the creation of market-specific material to the organisation of joint lectures and training courses.

Senzime works strategically with market launches based on factors including number of surgeries in the country, technological maturity, economic conditions and local registration requirements.

Integrated medical devices are valuable assets in patient care and a form of collaboration that Senzime continuously evaluates. The Company is collaborating with Philips on the implementation of a communication platform between TetraGraph® and Philips IntelliVue patient monitors globally, which was launched at the end of 2019. The Company is aiming to implement more communication solutions moving forward, all designed to make it easier for users to share data.

Since the fourth quarter of 2021, TetraGraph® has been manufactured in Senzime's own production premises in Uppsala, Sweden, and the Company is now relocating the manufacture of ExSpiron® to its premises in Uppsala. The relocation is scheduled for completion during the first quarter of 2023. TetraSens® is manufactured by the Dutch manufacturer Technomed Engineering BV and TetraSens® Pediatric is manufactured by the Swedish manufacturer Nile AB. OnZurf® is manufactured by the Italian company Moss S.p.A.

Senzime has an exclusive license agreement with Japanese company Fukuda Denshi Co. Ltd ("Fukuda"), under which Fukuda licenses Senzime's TetraGraph® technology for the exclusive commercialisation of private label portable products on the Japanese market. Fukuda also holds exclusive rights in Japan to, in a next step and at own expense, integrate Senzime's TetraGraph® technology with Fukuda's larger monitoring system. Fukuda buys components directly from designated suppliers, and Senzime therefore does not keep any stocks for Fukuda, incur any costs of goods sold or have any other working capital requirements related to the agreement.

The Company also has a license agreement with Italian company Moss S.p.A, giving the licensee a ten-year manufacturing and sales right to the Company's OnZurf® Probe product in Europe. As a result of the out-licensing agreement, Senzime has transferred legal manufacturing rights and related product liability for OnZurf® to Moss S.p.A, including future development costs. Senzime retains the patent rights and the right to commercialise OnZurf® in all markets outside Europe.

The Company has had a license agreement with US company Masimo since 20 June 2022. Under the agreement, Senzime has the right to use certain intellectual property rights from Masimo to develop, manufacture, market and distribute products that can be connected to the Root® patient monitoring system with related connectivity hub for transferring data to the hospital's EMRs. This hub includes Masimo's Hospital Automation™ and iSirona™ products. Other expansion modules from Masimo that are available for Root® include SedLine® brain function monitor, NomoLine® capnography and O3® regional oximetry.

Senzime intends to use the rights under the license to develop a new cable module – the TetraGraph® Smart Cable Module – that connects the TetraGraph® system to Masimo's Root® system.

TetraGraph® Smart Cable Module will eliminate the need for the monitor in the TetraGraph® system and enable the use of the Company's TetraSens® electrodes with the Root® system. Root® is sold worldwide with a rapidly growing installed base and is now the standard system in many hospitals.

The collaboration with Masimo is a strategic partnership between the companies in which both parties will work together to raise awareness of TetraGraph® Smart Cable Module, and of the solutions for connecting the TetraGraph® system to Masimo's system. The Board of Directors in Senzime believes that this partnership will broaden the awareness of TetraGraph® and expand the addressable market. The agreement and collaboration are described in more detail in the full prospectus, under the section "Significant Agreements".

In addition to relevant partnerships and collaborations, the Company believes that a key basis for successful market adaptation is to cooperate with Key Opinion Leaders, who evaluate and believe in the Company's technology and are willing to advocate TetraGraph® objectively.

In 2020, Senzime established both a scientific and clinical forum (a *Scientific Advisory Board" and a "Clinical Advisory Board"*), both were further developed in 2021 and 2022. By collaborating with the world's leading anesthesiologists, the Company is ensuring that it always lies at the forefront off technological and medical advances concerning continued product development. These forums also serve as an important platform for adjusting the Company's clinical strategy for TetraGraph®. Senzime conducts continuous studies, either in-house or by supporting research-initiated studies. The aim of these studies is to provide the market with further support for existing or new claims, or to validate new indications. The Company intends to continue deepening its contacts with national research centres.

Business model

The need for TetraGraph® and ExSpiron® is global and Senzime has based its strategy for registration and timing of market entry in various countries on several parameters at an early stage, of which market size, national guidelines, price level and technological maturity have been particularly important. Regulatory complexity and ability to collaborate with an established distributor have also played a role.

The Company's sales strategy is to speed up sales of monitors to hospitals and focus on the use of disposable sensors, which leverages recurring revenue and is also the basis of the business model.

TetraGraph® is now available in 29 countries and ExSpiron® in 22 countries, where the key markets are the US, Germany, France, Italy, the UK, Spain, Switzerland, South Korea and Japan. The business model framework comprises three key components: licensing, distribution and own sales organisations.

Licensing

In Japan, Senzime entered into a partnership with Fukuda, a world leader in patient monitoring, as early as 2016 via the Company's

Acacia Designs B.V. subsidiary. The business model in Japan is license-based, which means that Fukuda gains access to Senzime's TetraGraph® technology for exclusive commercialisation of the product in the Japanese market.

Distribution

In 2018, Senzime entered into a distribution agreement with Unimedics in South Korea. Unimedics' unique complementary product portfolio with monitors for measuring the depth of neuromuscular block during anesthesia are a perfect fit for TetraGraph®. Since 1 March 2021, the South Korean government's reimbursement scheme has included Senzime's type of disposable sensors for anesthesia with muscle relaxant drugs in patients with ASA-PS 3 or higher. This means that hospitals receive public funding for the one-time cost that each TetraSens® disposable sensor incurs when used to monitor depth of anesthesia in this patient cohort, thereby making them cost-neutral for hospitals to use.

In the European focus markets (France, Germany, the UK, Italy, Spain, Switzerland and Belgium), the Company has agreements with the leading distributors of anesthesia devices in all countries except Germany, where the Company has established its own sales organisation (see below).

Senzime works very closely with its distributors, as if they were the Company's own sales representatives, by providing training and certification, and ensuring that the available marketing material meets national needs. For particularly important evaluations, Senzime sometimes participates and supports the distributor on site in the hospitals.

Own sales organisation

In the US, the Company has had a wholly owned subsidiary since 2020, Senzime Inc., where the business model is to sell directly to hospital and clinics. The US sales organisation in Senzime Inc. was expanded in 2021 and now consists of 13 people. The US is the largest medical devices market in the world with a 40 per cent share of global sales and more than 6,000 hospitals.

In January 2021, Senzime established a wholly owned subsidiary in Germany. In 2021, the German subsidiary employed three people and the organisation was expanded by another person during 2022. Germany is the largest medical devices market in Europe with a population of 82 million people and more than 2,000 hospitals.

As of 31 December 2022, the Group employed 49 people, of whom 26 in Senzime, 12 in Senzime Inc, 4 in Senzime GmbH and 7 in Respiratory Motion, Inc.