

A photograph of surgeons in an operating room. They are wearing blue scrubs, blue bouffant caps, and surgical masks. They are looking towards a patient on an operating table. Above them are large, multi-panel surgical lights with a blue and purple glow. A computer monitor is visible in the background. In the foreground, a smartphone is mounted on a stand, displaying a mobile application interface with various data points and graphs.

Annual Summary 2018



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Senzime in brief

Senzime develops unique medical device solutions that make it possible to assess patients' biochemical and physiological processes before, during and after surgery. Its portfolio of technologies includes bedside systems that enable automated and continuous monitoring of life-critical substances such as glucose and lactate in blood and tissues, as well as systems to monitor patients perioperatively. Senzime's solutions are designed to ensure maximum patient benefit, reduce complications associated with surgery, and cut health care costs. Senzime operates in growing markets, which are worth over SEK 10 billion in Europe and the US alone. Senzime AB's (publ) share is listed on Nasdaq First North.

Business highlights of 2018

Senzime signs collaborative agreement with Philips Health Care

Senzime signed a collaborative agreement with Philips to implement a communication platform between TetraGraph and Philips' IntelliVue patient monitors worldwide.

Senzime executes private placement

Senzime conducted a private placement for selected strategic investors, including Segulah Venture AB. This issue raised the company SEK 25 m before issue expenses (SEK 136,000).

Senzime signs distribution agreements on TetraGraph

Senzime signed exclusive distribution agreements on TetraGraph in Spain, Portugal and South Korea, the Netherlands, Luxembourg, Austria, the Czech Republic, Slovakia, Italy, Slovenia, Ukraine, Moldavia and Georgia in the year.

Pia Renaudin becomes Senzime's CEO

In November, the Board of Directors decided to appoint Pia Renaudin as Senzime's new Chief Executive Officer. Pia took up her position in the first quarter of 2019.

Senzime executes private placement

Senzime conducted a private placement to Handelsbanken Fonder through Svenska Microcapfond ('the Swedish Micro Cap Fund') and Länsförsäkringar Asset Management.

This issue raised the company SEK 27.6 m before issue expenses (SEK 1.8 m).

Milestone payment from Fukuda Denshi

Senzime reached a milestone in its partnership with Fukuda Denshi of Japan, and booked a milestone payment of approx. SEK 2.4 m in the exclusive agreement entered in 2016.



Highlights after the end of the financial year

Pia Renaudin becomes Senszime's new CEO

On 19 November 2018, Senszime announced the appointment of Pia Renaudin as its CEO. Pia took up her position in February, thereby succeeding Catrin Molund, the Interim CEO.

University Hospital of Umeå commences trial with OnZurf Probe

The University Hospital of Umeå commenced a new explorative pilot study on OnZurf Probe. This trial will enroll a total of 30 liver surgery patients.

Senzime updates and optimizes strategy for FDA approval

Senzime renewed its 510(k) application to reduce the lead-time to FDA clearance. The new application was filed in March.



Senzime launches TetraGraph Viewer

Launch of TetraGraph Viewer—new software enabling data transfer from TetraGraph to a connected computer.

Uppsala University Hospital—Senzime's new strategic customer

The Neuroanesthesia Department of Uppsala University Hospital has signed an agreement to purchase the TetraGraph system. Initially, this agreement is of lesser value and for five TetraGraph systems with the associated disposable sensors.

Senzime files new FDA application for TetraGraph

The company filed a new 510(k) application with US regulator the FDA, consistent with the company's strategy of reducing the lead-time for FDA clearance, to then launch TetraGraph on the US market.

Senzime makes new marketing & sales appointments

Senzime strengthens its management team with a new VP of Sales and VP of Marketing & Business Development.

High demand for our products

My first two months as CEO of Senszime have been an intensive phase, with numerous meetings in-house and externally, to gain an initial view of the company, our products and the market we operate in. I see great potential.

I feel pride when I see how committed and professional our people are, and when I meet customers who tell me how our products ease their work, while also making patient care safer.

One of the cornerstones of our commercialization phase is our appointment of Anders Selin as VP of Sales, and the promotion of Catrin Molund to VP of Marketing & Business Development. This is the first step in a process I've initiated to give us structure and bring the optimal potential for growth.

In Europe, we work close to distributors, who extend our reach to end-customers. We've selected a few markets for additional focus initially, where we're putting in a little more time to get close to end-customers. Sweden is one of these markets, where we've sold instruments to a number of major hospitals, including Uppsala University Hospital.

In the first quarter, we also filed a new application for TetraGraph with the FDA, and expect clearance in the year. In parallel, we're also making major efforts on strategic and practical preparations for a US launch, which will be immediately after approval.

In Asia, our Japanese licensing partner is preparing for a market launch of TetraGraph, once approval from the Japanese regulators has been secured, which we anticipate after summer 2019. Our Korean distributor is also expected to secure regulatory approval in the year, with sales start scheduled at the end of the final quarter.

During the year, Senszime collaborated with several eminent anesthesiologists and surgeons, who are attracted by the potential our products offer in terms of precision, user-friendliness and clinical potential. Through these collaborations, we want to ensure that our products not only alleviate the current problems related to a high level of complications due to inadequate monitoring, but also keep pace with the technological and clinical progress of future surgery.

Our focus is on patients, and working with products that cut complications and costs is fantastic. Thank you for joining us on our journey!

Pia Renaudin, CEO

Uppsala, Sweden, April 2019

“We have many years of research under our belt, a great team, plus several distributors and licensing agreements in place.”



Operations and market

Operations

Senzime is a Swedish medical device company with unique products and solutions that enable monitoring of patient biochemical and physiological processes before, during and after surgery. Its solutions are designed to maximize patient benefit, reduce complications during surgery and cut the cost of health care. Senzime's portfolio includes patient-oriented solutions that enable automated and continuous measurement of biological substances such as glucose and lactate in blood and tissues, as well as bedside systems for monitoring patient neuromuscular function under anesthetic in combination with muscle relaxants (NMBAs).

Business concept—enabling critical monitoring for life

Our focus is the patient. We prevent complications, help shorten hospital stays and reduce the costs of health care. But first and foremost, we alleviate suffering and save lives.

Applying innovative digital solutions, we develop new methodologies to ensure and specify outcomes that streamline existing operations and generate cost savings for users. Ultimately, this promotes better quality of life of the patient and superior treatment outcomes in the health care system.

Business model

Senzime develops medical devices and the associated consumables. The company conducts preclinical and clinical trials in-house, but most manufacture is outsourced. Sales are through distributors in Europe and Asia, with launch scheduled in the US for 2019. We continuously screen new acquisition targets.

Market

Senzime develops medical devices designed to ensure maximum patient benefit, reduce complications in surgery and cut the costs of health care. The company operates on growth markets

that are worth over SEK 10 billion in Europe and the US alone.

TetraGraph

Neuromuscular blocking agents (NMBAs), are used worldwide as adjuncts to general anesthesia in over 70 million patients every year. Clinical trials demonstrate that some 30-60% of these patients are affected by complications due to residual effects from NMBAs, causing muscle weakness, compromised oxygenation and breathing difficulties. There is a pressing global need on the market for a simple, objective neuromuscular monitor that indicates when patients can be taken off a ventilator without a risk of complications. Of the total of some 400,000¹ operating theaters in the world, some 140,000 represent our primary target group for neuromuscular monitors.

Products

TetraGraph

TetraGraph is an innovative and user-friendly CE-marked system to monitor patients in general anesthesia with NMBAs. The system enables the objective determination of correct dosages of muscle relaxants, helping physicians determine when a patient has recovered sufficiently for spontaneous breathing.

TetraGraph is designed to monitor the effects of NMBAs simply and precisely, and to reduce postoperative complications and costs of health care. The system consists of a portable, hand-held patient monitoring unit and disposable sensors.



CliniSenz Analyzer

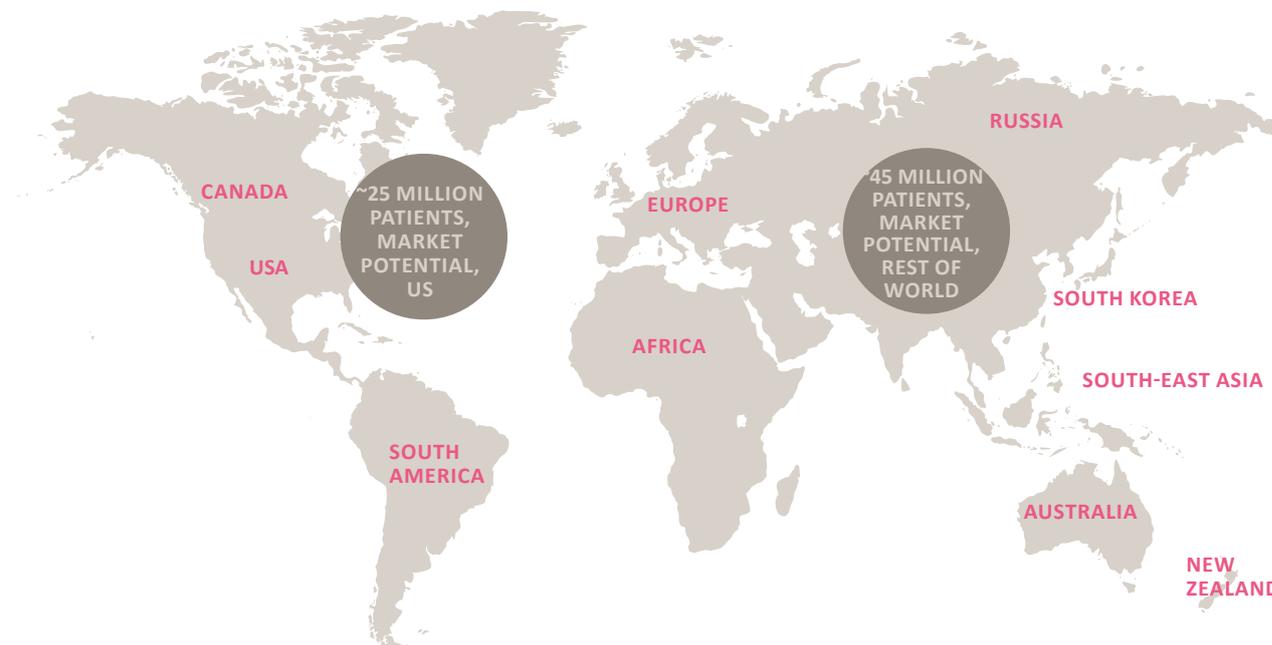
CliniSenz Analyzer is the future of postoperative and continuous patient monitoring in hospital environments. The system requires only small sample volumes for analysis, and CliniSenz Analyzer's results are specific, with high precision. The Analyzer utilizes enzyme-based heat flows, which reduces the risk of interference from other compounds such as pharmaceuticals. CliniSenz Analyzer is used in tandem with OnZurf Probe and other microdialysis catheters. CliniSenz Analyzer is currently in development.

OnZurf Probe

OnZurf Probe is a CE-marked product based on micro-dialysis technology that enables continuous sampling from an individual organ. OnZurf Probe is a unique micro-dialysis catheter for clinical applications, which is fixed to the surface of the organ without penetrating the tissue and causing unnecessary organ stress.



TetraGraph—market potential



A total of 51.4 million surgical procedures are conducted in the US each year (www.cdc.gov). Some 50% of these procedures required general anesthesia at the use of NMBAs. Conservative estimates based on US data indicate that there are another 45 million surgery cases requiring the use of NMBAs in the rest of the world, a total of 70 million surgery cases each year (Ishizawa Y, 2011).

The endpoint of a clinical trial on 100 patients demonstrated that quantitative (objective) neuromuscular monitoring reduced the incidence of postoperative complications by 52%. The need for emergency reintubation was also obviated.

Source: Todd MM, Anesth Anlag 2014

Postoperative respiratory complications are the second most common surgical complication after wound infection, and create a major economic burden for hospitals and patients.

Source: Dimick JB, 2004

The average cost of surgery for patients without airway complications in the US is USD 5,015, which increases by a factor of 12 to USD 62,704 for patients that experience respiratory complications.

Source: Kuhri SF, 2005, Ramachandran sK, 2011, Smetana GW, 2006

OnZurf Probe and CliniSenz Analyzer

An aging population and growing incidence of cancer worldwide is accentuating the need for advanced procedures such as colorectal surgery and organ transplantation. There is a clinical need for a more effective methodology to detect complications post-surgery in the target organ. By monitoring the organ directly, we can identify high levels of lactate, which is a good indication of organ oxygen deficiency. Early detection offers the opportunity of earlier diagnosis, and thus more rapid action.

Senzime has developed user-friendly products for continuous measurement of glucose and lactate. Their measurement is critical for discovering complications such as ischemia and anastomotic leakage (intestinal content leaking into the abdomen) postoperatively.

There are a total of some 366,000 intensive care beds globally, with the US and Europe being the two biggest markets with 88,000 and 83,000 respectively.

Patents

Intellectual property is an important component of Senzime's business. Senzime Protect's operations with patents and trademark registration.

- Senzime's biosensor platform (including sensor) and enzyme reaction is protected by patents in Germany, the UK, the US, Switzerland, France, the Netherlands and Sweden.
- Senzime has been granted method and device patents (OnZurf Probe) in Japan, the US, Germany, the UK and Sweden.

- Senzime has been granted patents on its improved microdialysis probe (OnZurf Probe) in Sweden. The application is under consideration for other countries.
- Senzime holds a patent on TetraSenz in the US. The patent is in process in Europe.
- Senzime also has current patent filings on TetraGraph.
- Patent protection will remain important to future operational development, and Senzime will be working to protect its research and development investments through additional patents.

Senzime has registered the trademarks of OnZurf, CliniSenz, TetraGraph and TetraSenz in the EU and US.

¹ Global operating theater distribution and pulse oximetry supply: an estimation from reported data. L M Funk, T G Wisner et al

Partnership with the University of Debrecen

Senzime has had a successful partnership with the Department of the Anesthesiology and Intensive Care at the University of Debrecen for many years. An interview with Bela Fulesdi, a Professor at the Department, and Chair of the Hungarian Health Ministry's Scientific Council, follows

How did the partnership with TetraGraph begin?

It all started with an article I wrote in the US periodical *Anesthesiology* in July 2013. Professor Sorin Brull of Mayo Clinic, one of TetraGraph's inventors, wrote the introduction to that issue, and we met personally a few months later. Our shared interest in monitoring patients under neuromuscular blockade has triggered several studies on this subject over the years

Why is monitoring patients under neuromuscular blockade perioperatively and postoperatively important?

Studies indicate that as many as 30-50% of patients experience some form of complication due to residual blockade, and 1% will experience a critical respiratory event, which is a life-threatening complication. Monitoring these patients can significantly reduce the incidence of complications such as pneumo-



nia, which is both unpleasant and potentially life-threatening for patients who are already physically weakened.

From the side of health care provision, there are other benefits in ensuring the right dosages of NMBAs, documenting that patients have not been extubated with residual blockade, and tailoring reverse drug dosages when the return of full muscle strength is desired. Overall, fewer complications result in shorter hospital stays and reduced costs.

There are different methodologies for monitoring patients with neuromuscular blockade, what are the benefits of TetraGraph?

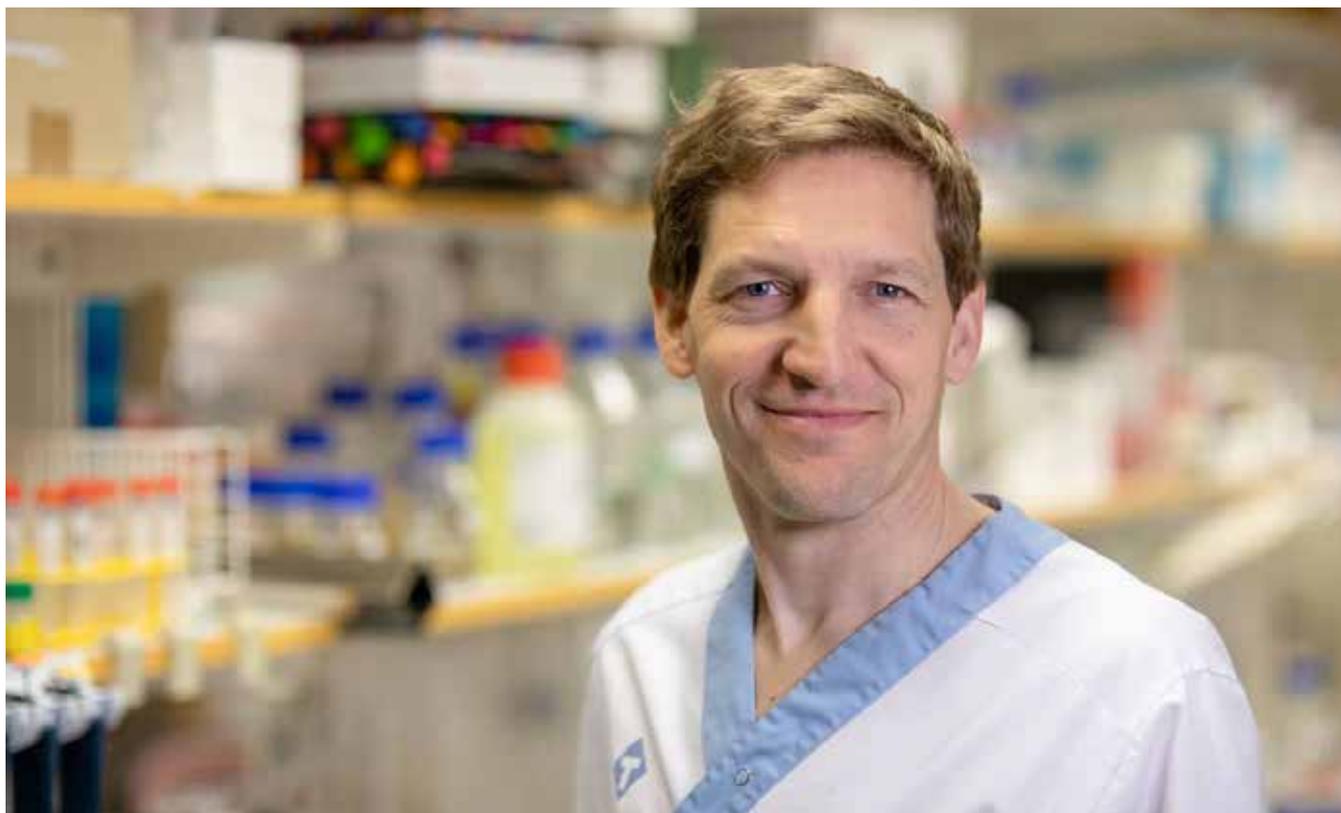
Many physicians still use subjective assessments to prevent complications, i.e. relying on their own judgement tests. The literature clearly indicates that this is not a safe and effective method. The difference an objective monitor offers is that it generates a quantitative metric. There are a number of objective methodologies such as AMG (acceleromyography) based on movement technology and EMG (electromyography), the latter being a more precise method. TetraGraph (and EMG) offer several benefits:

- faster start-up (30 sec. v. 3-10 min.), a very significant factor in operating theaters
- works in all types of surgery, even when the arm needs to be placed under surgical sheets. This is not possible with AMG technology, which is based on movement, and the hand needs freedom of movement.
- easier application of sensors, because they are specifically designed for this purpose.

What's the future for TetraGraph?

TetraGraph represents the care standard of the future; easy to use, easy to install, precise and with disposable electrodes, which is the current trend in health care, where infection control is becoming increasingly important.





Liver monitoring with microdialysis

As Senzime previously announced in a press release on 25 March 2019, the University Hospital of Umeå has commenced a study on OnZurf Probe. We interviewed consultant Oskar Hemmingsson, who is managing the study:

What makes microdialysis interesting?

Getting a momentary insight into the specific metabolism of the liver, instead of taking a general blood sample that reflects the status of the whole body, is really exciting.

Which problem could microdialysis solve?

I can see microdialysis helping us monitor how certain parts of the body are doing post-surgery. Also, microdialysis can give us more fundamental knowledge about the metabolism of healthy and diseased liver tissue, which eventually, could be significant to increasing

our understanding of tumor disease and liver disease.

What are the most common complications in liver surgery?

One of the most feared complications is liver failure. It isn't very common, but can occur when too much of the liver is excised. If severe liver failure occurs, there's no good treatment.

How could OnZurf probe make things better for surgeons?

- If we can learn to monitor the liver better perioperatively, we'll gain a better perception of its function.
- If we can establish a method to compare metabolism in a healthy and diseased liver, we can find out more about the fundamental mechanisms of disease, so OnZurf could become an important tool for research.

- Organ rejection can occur after liver transplantation, so improved monitoring of liver metabolism using OnZurf could offer potential value.
- On occasion, we need to shut off the blood supply to the liver during surgery. Potentially, OnZurf could enable us to monitor how long this is possible for without damaging the liver.

Do you see any advantages of OnZurf probe compared to alternatives?

OnZurf obviates the need for insertion into tissue, which is a benefit in tumor surgery. When measuring tumors, it's better not to insert, because there is a risk of tumor cells spreading. Insertion into the liver risks bleeding, and local leakage of gall, which theoretically, could disrupt the results of microdialysis, and this should be reduced with surface measurement.

Board of Directors and senior management



Philip Siberg

Chairman of the Board
Chairman since 2016

Location: Stocksund, Sweden

Born in: 1973

Education: M.Sc. (Eng.), Royal Institute of Technology, Stockholm (1997)

Main occupation: Philip serves as CEO of Coala Life AB.

Other assignments: Philip is CEO and Deputy Director of Longmeadow Farm AB, independent CEO of Coala-Life.

Previous experience: for the past five years, Philip has served as CEO of Acacia Designs, CEO of Stille AB (publ.), CEO and Chairman of Dipylon Medical AB (formerly CMA Microdialysis AB), Director of Dipylon AB (liquidation completed on 27 November 2014) and Stille Incentive AB.

Holdings in the company: Philip Siberg holds a total of 882,989 Senszime shares personally and through Longmeadow Farm AB.



Adam Dahlberg

Director
Director since 2000

Location: Blankaholm, Sweden

Born in: 1973

Education: MBA, Stockholm School of Economics (1998)

Main occupation: Adam conducts investment activities, property ownership and agriculture.

Other assignments: Adam is Chairman of PiezoMotor Uppsala Aktiebolag (publ) and Corline Biomedical AB, a Director of Corline Pharma AB, Mörtfors Fiber ekonomiska förening, Wirums Säteri AB, Silotornet AB, Your Ocean AB and Wirum Gårdsprodukter AB. Adam Dahlberg is also a Deputy Director of Carl Rosenblad Racing AB.

Previous experience: for the past five years, Adam has served as Chairman of Senszime AB (publ).

Holdings in the company: Adam Dahlberg holds 3,151,907 Senszime shares. Additionally, Ebba Fischer holds 2,142,229 shares, the Crafoordska Foundation 1,606,943 shares, Margareta Nilsson 1,575,184 shares, Anna Manhusen 1,345,870 shares and AB Pethle 416,573 shares of the company, all of whom are related parties of Adam Dahlberg.



Ulf Lindskog

Director
Director since 2010

Location: Ulricehamn, Sweden

Born in: 1944

Education: high school graduate, Praktiska Realskolan Borås (1961)

Main occupation: Ulf Lindskog served as CEO of Ulfabgruppen AB and has been active in pre-hospital emergency care for over 40 years. Ulf also served as VP of Sales for SweTeco.

Other assignments: Ulf Lindskog is a Director and CEO of Frelind AB and Chairman of Aweria, Name-U Invest AB and Premedic Östergötland AB. Ulf Lindskog is also a Director of Investment Aktiebolaget Chiffonjén, Mo LSS Aktiebolag, Investment AB Vitrinen, Boel & Jan Holding AB, Mo Gård AB and Göteborgs Fabrikerna AB.

Previous experience: for the past five years, Ulf Lindskog has served as Chairman of MUDDUS Outdoor Sweden AB and Göteborgs Fabrikerna AB, as well as a Director and Deputy Director of Home of Textile Scandinavia AB. He has also served as a Director of Premedic Östergötland AB.

Holdings in the company: Ulf Lindskog holds 3,000,000 shares of the company. Additionally, Nina Lindskog holds 400,000 shares, Anette Gustafsson 400,000 shares, Michael Lindskog 331,750 shares, all of whom are related parties of Ulf Lindskog.



Sorin J. Brull

Director
Director since 2016

Location: Florida, USA

Born in: 1956

Education: Medical School, WVU (1984), Residency (Anesthesia), Yale University (1987), Fellowship, Yale University (1988)

Main occupation: Sorin J. Brull Serves as an anesthesiology consultant. He is also Professor of the Mayo Clinic College of Medicine and was formerly Head of Department at the University of Arkansas for Medical Sciences (UAMS) and Divisional Head of the Yale School of Medicine.

Other assignments: Sorin is a Director of the Anesthesia Patient Safety Foundation (APSF). He is also a member of the Scientific Advisory Board of The Doctors Company (Medical Malpractice Insurer) and ClearLine MD (Medical Device Company).

Previous experience: in the past five years, Sorin has founded T4Analytics LLC, which was subsequently acquired by Acacia Designs. Sorin is also a founder of Acacia Designs, which merged with Senzime AB.

Holdings in the company: Sorin J. Brull holds 4,116,821 shares of the company personally and through Pensco Trustee for S Brull.

Other: Sorin J. Brull acquired shares of the company as part of the merger between Senzime and Acacia Designs. He is also a party to an agreement with Senzime AB on consulting services.



Lennart Kalén

Director
Director since 2018

Location: Stockholm, Sweden

Born in: 1947

Education: Master of Science, MBA and studies at IMI Geneva. Engineer in Building Technologies.

Main occupation: Lennart serves as Deputy Chairman of AB Segulah and Chairman of Segulah Venture AB.

Other assignments: Lennart Kalén is Chairman of Balco Group AB (Nasdaq), Optolexia AB and a Director of Sanbäckens Holding AB

Previous experience: Lennart has served in executive roles internationally for SKF, ABB Fläkt, Alfa Laval, Dahl Sverige/Saint Gobain, and has served as Chairman of DoCu Nordic AB, NEA AB, Previa AB and Sankt Eriks AB.

Holdings in the company: Lennart Kalén represents 3,360,000 shares, of which 360,000 shares held through his own company, 2,250,000 shares via Segulah Venture AB and 750,000 shares via AB Segulah.

Other: For the past 20 years, Lennart has served in positions including Industrial Partner for Segulah Adviser AB, offering advisory services for private equity funds.



Pia Renaudin

Chief Executive Officer since 2019

Location: Bromma, Sweden

Born in: 1967

Education: MBA, the University of Gothenburg (1992), Graduate of INSEAD

Background: Pia possesses broad-based experience of the life science industry, focusing on marketing and sales. She previously held executive positions globally and regionally in Sweden and France. She started her career with AstraZeneca, and has led strategic product launches for companies including Bristol Myers, Squibb, Gilead Sciences and Styker.

Holdings in the company: Pia Renaudin holds no shares, share warrants or other share-based financial instruments of the company. The intention is for Pia to be offered the opportunity to subscribe for options in a share warrant program in 2019.

The share, share capital and ownership

Share price performance



Share capital history

Date	Event	No. of shares	Share capital (SEK)	Quotient value (SEK)
1 Jan 2018	Opening	40,694,223	5,086,778	0.125
22 Mar 2018	Private placement	44,860,893	5,607,612	0.125
4 Jul 2018	Share subscription through share warrants	45,077,503	5,634,688	0.125
21 Dec 2018	Private placement	49,077,503	6,134,688	0.125
Total, 31 December 2018		49,077,503	6,134,688	0.125

Ownership structure as of 31 December 2018

Name	No. of shares	Votes and capital (%)
Pershing LLC.	4,125,462	8.4%
Sorin J. Brull	4,116,821	8.4%
Adam Dahlberg	3,151,907	6.4%
Ulf Lindskog	3,000,000	6.1%
Stone Bridge Biomedical	2,996,586	6.1%
Segulah Venture AB	2,350,000	4.8%
Ebba Fischer	2,142,229	4.4%
Länsförsäkringar Fondförvaltning AB	2,000,000	4.1%
Handelsbanken Fonder AB	2,000,000	4.0%
Crafoordska Foundation	1,606,943	3.3%
Other	21,587,555	44.0%
Total	49,077,503	100.0%

Statutory Administration Report

The Board of Directors and Chief Executive Officer of Senszime AB, with corporate identity number 556565–5734, hereby present the annual accounts and consolidated accounts for the financial year 2018. Unless otherwise stated, all amounts are in thousands of Swedish kronor (SEK 000), and are for the group. Figures in brackets are for the financial year 2017, unless otherwise stated.

Operations

Senzime is a medical device company active in patient monitoring. Senszime was founded in 1999 on the business concept of developing bedside systems for measuring life-critical substances. In 2001, members of the Crafoord family, represented by Adam Dahlberg, became partners in the company. In 2004, Senszime completed its first prototype for clinical measurement of blood sugar levels for health care.

Senzime's early initiatives in biotechnology made contributions to knowledge and were significant to the validation and verification of the technology platform. However, Senszime decided to focus its operations primarily on the health and medical care segment, and is not making further investments in biotechnology.

The company MD Biomedical AB was acquired in 2015. MD Biomedical AB was founded in 2011 and has developed and patented OnZurf Probe, a new generation of microdialysis catheter.

Acacia Designs B.V. was acquired in spring 2016, and operations were extended to also include solutions for monitoring patients under general anesthetic, often a similar patient group to Senszime's other products. Senszime's product portfolio currently consists of three product families in two different segments.

In its Clinical Diagnostics segment, Senszime develops bedside systems that enable automated and continuous monitoring of life-critical substances such as glucose and lactate in the blood and tissues. Senszime's patient monitoring systems are primarily targeted at health care, and are based on its patented biosensor technology. Senszime's CliniSenz Analyzer and OnZurf Probe products enable the detection of post-operative complications significantly earlier than when applying conventional methodologies, and accordingly, can help improve patient safety and reduce the costs of health care.

In its Peri- & Post-operative Care segment, Senszime is developing a system to monitor the level of myoparalysis in patients under general anesthetic with the aim of reducing complications. Senszime's TetraGraph system enables the correct drug dosages to be administered, and objectively determine when it is safe to wake the patient and allow spontaneous breathing. TetraGraph has been developed to improve patient monitoring simply, and with high precision, with the resulting reduction in post-operative complications and costs of care.

Business highlights in the financial year

Business highlights in the first quarter

- January 2018. Senszime signs a licensing and collaborative agreement with Philips.
- February 2018. Senszime conducts a private placement totaling SEK 25 m for investors including Segulah Venture AB.
- March 2018. Senszime Signs distribution agreements for TetraGraph in Spain, Portugal and South Korea.

Business highlights in the second quarter

- April 2018. Senszime signs distribution agreements for TetraGraph in the Netherlands, Luxembourg, Austria, the Czech Republic and Slovakia.

Business highlights in the third quarter

- September 2018. Senszime signs distribution agreements for TetraGraph in Italy, Slovenia, the Ukraine, Moldavia and Georgia.

Business highlights in the fourth quarter

- November 2018. The Board of Directors appoints Pia Renaudin as new CEO.
- December 2018. The Board of Directors decides on a private placements for Handelsbanken fonder and Länsförsäkringar Asset management. This issue raises SEK 27.6 m for the company before issue expenses.
- December 2018. Senszime invoices Fukuda Denshi SEK 2.4 m for a milestone payment.

Business highlights after the end of the fourth quarter

- February 2019. Senszime intends to renew its current 510 (k) application with the FDA. Based on an updated version of TetraGraph, the existing 510 (k) application will be renewed with the aim of reducing the lead-time to clearance.
- March 2019. Senszime announces that the Neuroanesthesia Department at Uppsala University Hospital has signed an agreement to purchase the TetraGraph system.
- March 2019. The University Hospital of Umeå commences a new explorative pilot study on OnZurf probe.
- March 2019. Launch of TetraGraph Viewer—new software enabling data transmission from TetraGraph to a connected computer.
- March 2019. The company files a new 510(k) application with the FDA, consistent with its strategy of reducing the lead-time for obtaining FDA clearance.
- March 2019. Senszime announces new appointments to management, a VP of Sales, and a VP of Marketing & Business Development in the year.

The company's expected future progress and risk factors

A number of risk factors may have a negative impact on Senszime's operations. Accordingly, it is very important to consider relevant risks in addition to Senszime's growth potential. A number of risk factors, which are not arranged in order of importance, and make no claims as to completeness, follow:

Key individuals

Senzime is a small and knowledge-intensive business enterprise, and is dependent on a number of key individuals to achieve success. If one or several key individuals leaves Senszime, this may have negative consequences for operations, and results of operations.

Distributors, suppliers and other collaborative partners

Senzime bases its strategy on activities including development and sale jointly with distributors, licensees and other collaborative partners. If it is not possible to create existing or future partnerships, they are not achievable or do not function as intended. Senzime's commercialization potential would be negatively impacted. Senzime also has partnerships with suppliers. If one or several of these parties decided to discontinue a partnership, this would negatively impact operations.

Technology and product development

Senzime's products are in an early commercialization phase. Even if substantial efforts are made to assure the technology utilized, the possibility that complementary or alternative technological solutions will be necessary cannot be ruled out. This means that development work in addition to that already planned would be necessary.

Patents and intellectual property matters

Senzime's value is highly dependent on its capability to secure and defend patents and other intellectual property. Patent protection may be uncertain and involve complex legal and technical issues. There is a risk that patents are not granted on patent-pending inventions, that granted patents do not offer sufficient protection, or granted patents are circumvented or invalidated. Usually, previously granted patents are associated with substantial costs to conduct processes to protect validity, and where boundaries to potential infringement on Senzime's part or against competing companies' patents or for any infringement from external parties against Senzime's patents. With access to greater financial resources, competitors may be in a better position than Senzime to meet such expenses. If Senzime is unsuccessful in obtaining or defending patent protection of its inventions, competitors may be able to use Senzime's technology freely, which would negatively impact its capability to commercialize operations.

Confidentiality and commercial secrets

Senzime is dependent on commercial secrets not covered by patents, patent filings or other intellectual property. Such commercial secrets include information on discoveries where patents have not yet been filed. Even if employees and collaborative partners are normally covered by non-disclosure agreements with Senzime, there is a risk that a party with access to confidential business information reveals or otherwise uses it in a manner that damages Senzime, which may negatively impact operations, financial position and results of operations.

Financial risks such as liquidity, credit, currency and interest rate risk

Senzime's accounts receivable are associated with credit risk, where there is a risk of payment being delayed or of payment default. Senzime operates internationally, and a high share of sales are assumed to be in currencies other than Swedish kronor. If a customer does not pay or exchange rates are unfavorable for Senzime, this may negatively impact its financial position and results of operations.

The acquisition of Acacia Designs also means the group has substantial intangible assets denominated in euros. Changes in the relationship between the Swedish krona and euro may impact the group's consolidated net equity negatively. Senzime currently has no interest-bearing assets or liabilities.

Need for finance and working capital, and financing risk

The company is in a start-up phase, where expected revenues do not cover planned expenses. There is a risk that in future, Senzime may also need to raise further capital. Access to further finance is affected by a number of factors such as market conditions, general access to credit, Senzime's credit rating and credit capacity. Disruptions and uncertainty on the capital and credit markets may also limit access to the capital necessary to conduct operations. If, in future, Senzime is unsuccessful in raising the necessary capital for the company on reasonable terms, its operations, financial position and results of operations could be negatively impacted.

To the extent Senzime raises further finance through issuing shares or share-based instruments, Senzime's shareholders will be affected by dilution to the extent such new issues are conducted waiving shareholders' preferential rights.

Finance

The Board of Directors' opinion is that its current finance, even assuming some increase in sales, is sufficient to conduct operations in 2019. However, further finance in the form of loans or other external finance could be expected to be necessary to address the need for working capital and potential further investments in 2019.

Financial information

Revenues and earnings

Sales revenues amounted to SEK 3,214,000 (189,000) in 2018. SEK 2.4 m of sales revenues consist of a milestone payment from Fukuda Denshi of Japan, under the exclusive licensing agreement entered in 2016. Most of the remaining revenues are from the sale of the TetraGraph system on the European market. EBIT in 2018 was SEK -26,763,000 (-13,027,000). Most expenses are personnel and consulting expenses. The increase of personnel expenses is due to four staff appointments in 2018, and salary during the departing CEO's notice period. Amortization of development expenses for the TetraGraph system commenced in the third quarter of 2018. SEK 4,909,000 of amortization was charged to cost of goods sold in the Consolidated Income Statement for 2018.

Financial position

At year-end, consolidated equity was SEK 167.4 m (140.5), and the equity/assets ratio was 84.9% (84.6).

Cash flow and investments

Cash flow from operating activities including changes in working capital for 2018 was SEK -17,733,000 (-12,292,000). The increase of negative cash flow from operating activities is due to an increased deficit.

Cash flow from investing activities for 2018 was SEK -9,439,000 (-10,028,000).

Cash flow from financing activities for 2018 was SEK 51,100,000 (21,031,000). The increase is due to the two private placements executed in 2018. On 22 March 2018, Senszime conducted a private placement of SEK 25 m before issue expenses (SEK 136,000) to Segulah Venture AB, and a number of the company's principal shareholders. Accordingly, share capital increased by SEK 520,833 to SEK 5,607,612. On 21 December, Senszime conducted a private placement of SEK 27.6 m before issue expenses (SEK 1.8 m) to Handelsbanken Fonder through Svenska Microcapfond and Länsförsäkringar involving a total of 4,000,000 new shares. Accordingly, share capital increased by SEK 500,000 to SEK 6,134,688. At year-end, the company's cash and cash equivalents were SEK 32.7 m (8.7). The current cash position is considered sufficient to meet the needs of operations for the next 12 months.

Stock options

Share warrants

Shares were subscribed through share warrants for Medtech Innovation i Umeå AB, through Pernilla Abrahamsson, on 4 July 2018. 200,000 share warrants of Senszime at a price of SEK 2.31 per share conferred Medtech Innovation with 216,610 new Senszime shares. Accordingly, share capital increased by SEK 28,000.

Staff stock options

The company has a staff stock option program for all permanent employees. In the period to 31 December 2020 inclusive, each stock option confers entitlement to subscribe for one new share at a price of SEK 8.80. The stock options were granted free of charge. The stock options require continued employment with the company and are non-transferable.

Based on the existing number of shares and all outstanding share warrants, the maximum dilution effect of the program, assuming all share warrants are exercised to subscribe for new shares, is 3.2%.

Parent company

Most of the group's operations are conducted through the parent company, with the two subsidiaries only holding certain rights, which are licensed to the parent company against payment of royalties. For the parent company, the intra-group restructuring resulted in the shares of Acacia Designs B.V. being impaired by SEK 13,100,000 (64,975,000) effective 31 December 2018. This impairment loss has no effect on consolidated earnings.

Five-year summary, group¹

SEK 000	2018	2017	2016	2015	2014
Sales revenue	3,214	189	1,628	153	541
Profit (loss) after financial items	-26,763	-13,027	-9,412	-7,583	-6,192
Total assets	197,157	166,032	156,312	47,803	46,318
Equity	167,408	140,459	131,871	45,810	44,081
Equity/assets ratio (%)	85	85	84	96	95

¹ The group was formed in 2015, and accordingly, comparative years are for the parent company.

For definitions of key indicators, see supplementary disclosures.

Proposed appropriation of profits

The following funds are at the disposal of the Annual General Meeting:

Share premium reserve	173,707,992
Accumulated profit (loss)	-80,627,603
Profit (loss) for the year	-34,893,910
Total	58,186,479

The Board of Directors proposes that the funds are appropriated as follows:

Dividends to shareholders of SEK 0 per-share, totaling	0
Carried forward	58,186,479
Total	58,186,479