



Interim Report January – September 2019
Senzime AB (publ)



January – September 2019 in brief

Senzime AB (publ), 556565-5734

Third quarter 2019

- Net sales amounts to KSEK 2,420 (155)
- Income after financial items amounts to KSEK -8,232 (-5,834).
- Earnings per share before dilution amounts to SEK -0.15 SEK (-0.12).
- Cash and cash equivalents per Sept 30, 2019 equal SEK 38.9 million (13.0).
- Number of shares per Sept 30, 2019 amounts to 52,448,290 (45,077,503)

January - September 2019

- Net sales amounts to KSEK 4,023 (543).
- Income after financial items amounts to KSEK -26,894 (-15,474).
- Earnings per share before dilution amounts to SEK -0.50 (-0.34).

Definitions. Earnings per share: Net income for the period divided by the average numbers of shares during the period. In parentheses describes comparative period last year. Unless otherwise stated, all information refers to the Group

Financial overview

KSEK	Jul - Sept 2019	Jul-Sept 2018	Jan-Sept 2019	Jan-Sept 2018	Full year 2018
Sales revenue	2 420	155	4 023	543	3 214
Income after financial items	-8 232	-5 834	-26 894	-15 474	-26 763
Earnings per share before dilution (SEK)	-0,15	-0,12	-0,50	-0,34	-0,58
Solidity (%)	-	-	88,1	86,1	84,9

Significant events during the period

- **February.** Pia Renaudin joins as new CEO at Senzime AB.
- **March.** The Department of Neuroanesthesia at the University Hospital in Uppsala signs an agreement to buy TetraGraph systems.
- **March.** Norrlands Universitetssjukhus initiates a new exploratory pilot study with OnZurf probe.
- **March.** Senzime launches the TetraGraph Viewer, a new software, enabling data extraction and analytics from the TetraGraph patient monitor to a connected computer.
- **March.** Senzime announces the filing of the new 510(k) application to the FDA for the TetraGraph system to decrease the overall time to reach FDA clearance and introduction on the US market.
- **March.** The Senzime management team is strengthened with VP Global Sales and VP Global Marketing and Business Development.
- **May.** Senzime signed an exclusive distribution agreement with Vingmed Holding A/S for the commercialization of TetraGraph in Sweden, Denmark, Norway and Finland.

- **May.** Senzime receives the first million order from South Korea.
- **June.** Senzime's board member Ulf Lindskog has passed away.
- **June.** Senzime contracts Erik Bergman as new CFO.
- **July.** TetraGraph receives regulatory approval and additional order from South Korea.
- **July.** Senzime increases focus on the market for anesthesia monitoring and communicates sales targets.
- **July.** Senzime proposes a directed share issue of SEK 30 million to Länsförsäkringar, Handelsbanken, Segulah and the Crafoord family.
- **August.** Extraordinary general meeting decides on the directed share issue.
- **August.** 100 TetraGraph systems to Japan after regulatory approval.

Significant events after the end of the period

- **October.** Senzime receives 510 (k) clearance by the US drug authority FDA. The clearance gives permission to market and sell TetraGraph in the US market.



About Senzime

Senzime develops and markets systems, driven by unique algorithms and sensors, to follow patients' nervous systems and electrical impulses – before, during and after surgery. The company's solution is called TetraGraph, a medical technology system that digitally and continuously measures the degree of neuromuscular blockade in the patient.

The goal is improved clinical precision and simplified management in healthcare. By preventing complications and enabling healthcare professionals to follow health care guidelines and drug recommendations, TetraGraph contributes to shorter hospitalizations and lower health care costs – in a world where everyone wakes up safely after surgery.

Senzime's development portfolio also includes innovative, patient oriented solutions that enable automated and continuous measurement of biological substances such as glucose and lactate in blood and tissue fluid.

The vision is a world without narcotics-related complications. Senzime operates in growing markets that in Europe and the United States are valued in excess of SEK 10 billion. The company's shares are listed on Nasdaq First North Growth Market (ticker SEZI)

TetraGraph

TetraGraph is a CE-labeled innovative and user-friendly digital system for monitoring patients undergoing anesthesia with neuromuscular blocking agents (NMBAs). TetraGraph is designed to easily and accurately measure the effects of NMBAs, helping the physician to decide on the degree of neuromuscular function in real time and thus when it is safe to wake the patient after surgery. The system consists of a portable, hand-held patient monitoring unit and disposable sensors.

By preventing complications and enabling healthcare professionals to follow care guidelines and drug recommendations, TetraGraph contributes to shorter hospital stays and lower healthcare costs - in a world where everyone wakes up safely after surgery. TetraGraph's potential market is estimated at 166,000 operating rooms, which carry out 79 million operations annually.

Statement from the CEO

The most important event so far during the year was of course the FDA approval of TetraGraph in the US. We can now start sales in the world's largest market, and I look forward to offering TetraGraph to the American Physicians.

In Quarter three the launch of TetraGraph accelerated with regulatory approval in both Korea and Japan. Our distributor in Korea followed up with additional orders and 100 TetraGraph systems were ordered by our Japanese license partner. The start of sales in Japan means that we will receive a milestone payment.

In Europe, intensive work is on-going to establish close and effective collaboration with key distributors in our focus countries Italy, Spain, France, the UK and Germany and the Nordic region.

The employees have a great enthusiasm and the management team is complete since the first of October. I have great confidence in our senior team, which I think is one of the most important prerequisites for successfully launching a new product.

In September our finances were strengthened with approximately SEK 30 million through a directed share issue. This will allow us to accelerate the roll-out of TetraGraph and to make recruitments of key staff in the US.

In the last quarter of the year, the highest priority will be the United States' launch, with the recruitment of a US General Manager who is expected to start in quarter one 2020 when the registration of our subsidiary is final. Market initiatives are already underway with exhibitions during the last quarter, both at the U.S. largest anesthesia Congress ASA's (American Society of Anesthesiology) annual meeting in October and PostGraduate Assembly in Anesthesiology (PGA) in New York in December.

All the essential ingredients for a global roll-out of TetraGraph are now in place and we are ready for the amazing opportunities we are facing.

Uppsala in November, 2019,

Pia Renaudin, CEO



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Consolidated Income Statement

KSEK	Not	Jul-Sept 2019	Jul-Sept 2018	Jan-Sept 2019	Jan-Sept 2018	Full Year 2018
Sales revenue		2,420	155	4,023	543	3,214
Cost of goods sold		-4,448	-2,609	-11,673	-4,134	-8,441
<i>of which goods</i>		-1,093	-96	-1,887	-1,015	-2,245
<i>of which salaries</i>		-157	-84	-345	-125	-338
<i>of which external services</i>		-84	-325	-129	-640	-420
<i>of which depreciation</i>		-3,114	-2,104	-9,312	-2,354	-5,438
Gross income		-2,028	-2,454	-7,650	-3,591	-5,227
Selling and administrative expenses	1	-6,314	-3,331	-19,461	-12,002	-21,646
Other operating income		182	63	569	325	372
Other operating expenses		-72	-112	-351	-205	-260
Operating income		-8,232	-5,834	-26,893	-15,473	-26,761
Financial income						
Financial expenses		-	-	-2	-1	-2
Total financial items		0	0	-1	-1	-2
Income after financial items		-8,232	-5,834	-26,894	-15,474	-26,763
Deffered tax		692	457	2,069	457	1,142
Net income		-7,540	-5,377	-24,825	-15,017	-25,621
Average number of shares before dilution		49,789,114	45,077,503	49,314,707	43,698,527	44,154,382
Average number of shares after dilution		49,899,114	45,077,503	49,424,707	43,698,527	44,154,382
Earnings per share before dilution, SEK		-0,15	-0,12	-0,50	-0,34	-0,58
Earnings per share after dilution, SEK		-0,15	-0,12	-0,50	-0,34	-0,58

Consolidated Balance sheet

KSEK	Note	30 Sept 2019	30 Sept 2018	31 Dec 2018
ASSETS				
Non-current assets				
Intangible assets		153,379	161,131	159,198
Machinery and equipment		134	193	179
Total non-current assets		153,513	161,324	159,377
Current assets				
Inventories		1,138	848	961
Accounts receivables		1,570	187	2,731
Other current assets		583	607	831
Prepaid expenses and accrued income		553	673	591
Cash and cash equivalents		38,927	13,047	32,666
Total current assets		42,771	15,362	37,780
TOTAL ASSETS		196,284	176,686	197,157
EQUITY AND LIABILITIES				
Equity		173,017	152,054	167,408
Provisions		17,412	20,166	19,481
Current liabilities				
Accounts payable		1,692	2,496	4,795
Other liabilities		1,157	633	1,148
Accrued expenses and prepaid income		3,006	1,337	4,325
Total current liabilities		5,855	4,466	10,268
TOTAL EQUITY AND LIABILITIES		196,284	176,686	197,157

Consolidated Statement of Changes in Equity

KSEK	Equity	Other contributed capital	Acc exchange rate diff	Retained earnings	Total equity
Opening balance at January 1, 2018	5,086	151,129	1,087	-16,883	140,419
Net income				-15,017	-15,017
Exchange rate differences on translation of foreign subsidiaries			794		794
Employee stock options				522	522
Rights issue	549	24,951			25,500
Issue expenses		-164			-164
Total equity at Sept 30, 2018	5,635	175,916	1,881	-31,378	152,054
Opening balance at January 1, 2019	6,135	201,180	1,856	-41,763	167,408
Net income				-24,825	-24,825
Exchange rate differences on translation of foreign subsidiaries			885		885
Employee stock options				347	347
Rights issue	421	29,579			30,000
Issue expenses		-798			-798
Total equity at Sept 30, 2019	6,556	229,961	2,741	-66,241	173,017

Consolidated Statement of Cash Flows

KSEK	Jul-Sept 2019	Jul-Sept 2018	Jan-Sept 2019	Jan-Sept 2018	Full Year 2018
Operating cash flow					
Income after financial items	-8,231	-5,834	-26,894	-9,356	-26,763
Adjustment for depreciations	3,129	2,119	9,356	263	5,497
Other adjustments for items not included in cash flow	87	-221	624	244	372
Cash flow after operating activities before changes in working capital	-5,015	-3,936	-16,914	-8,849	-20,894
Cash flow from changes in working capital					
Changes in inventories and work in progress	758	277	-177	-708	102
Changes in current receivables	-567	146	1,447	-47	-2,759
Changes in current liabilities	-198	-544	-4,413	249	5,818
Cash flow from operating activities	-5,022	-4,057	-20,057	-9,355	-17,733
Investing activities					
Acquisition of intangible fixed assets	-538	-3,644	-2,886	-6,882	-9,439
Cash flow from investing activities	-538	-3,644	-2,886	-6,882	-9,439
Financing activities					
New issue	29,657	500	29,204	21,031	51,100
Cash flow from financing activities	29,657	500	29,204	21,031	51,100
Changes in cash and cash equivalents	24,097	-7,201	6,261	4,794	23,928
Cash and cash equivalents at the start of the period	14,830	20,248	32,666	10,027	8,738
Cash and cash equivalents at the end of the period	38,927	13,047	38,927	14,821	32,666

Parent Company Income Statement

KSEK	Note	Jul-Sept 2019	Jul-Sept 2018	Jan-Sept 2019	Jan-Sept 2018	Full Year 2018
Sales revenue		2,420	155	4,023	543	3,214
Cost of goods sold		-1,679	-782	-3,396	-2,307	-3,875
<i>of which goods</i>		-1,093	-96	-1,887	-1,015	-2,246
<i>of which salaries</i>		-157	-84	-345	-125	-338
<i>of which external services</i>		-84	-325	-129	-640	-420
<i>of which depreciation</i>		-345	-277	-1,035	-527	-871
Gross income		741	-627	627	-1,764	-661
Selling and administrative expenses	1	-6,295	-3,223	-19,314	-11,699	-21,241
Other operating income		182	63	569	325	372
Other operating expenses		-72	-112	-351	-201	-261
Operating income		-5,444	-3,899	-18,469	-13,339	-21,791
Write-down of shares in group companies		-	-	-	-	-13,100
Financial income		-	-	-	-	-
Financial expenses		-	-	-2	-1	-3
Total financial items		0	0	-2	-1	-13,103
Income after financial items		-5,444	-3,899	-18,471	-13,340	-34,894
Net income		-5,444	-3,899	-18,471	-13,340	-34,894

Parent Company Balance sheet

KSEK	Note	30 Sept 2019	30 Sept 2018	31 Dec 2018
ASSETS				
Non-current assets				
Intangible assets		55,456	52,681	53,605
Machinery and equipment		134	193	179
Financial assets		11,218	24,088	11,010
Total non-current assets		66,808	76,962	64,794
Current assets				
Inventories		1,138	848	961
Accounts receivables		1,436	187	2,713
Other current assets		557	604	805
Prepaid expenses and accrued income		552	661	591
Cash and cash equivalents		38,486	12,793	32,231
Total current assets		42,169	15,093	37,301
TOTAL ASSETS		108,977	92,055	102,095
EQUITY AND LIABILITIES				
Equity		103,088	87,362	91,793
Provisions		-	-	-
Current liabilities				
Accounts payable		1,692	2,692	4,794
Other liabilities		1,212	708	1,203
Accrued expenses and prepaid income		2,985	1,293	4,305
Total current liabilities		5,889	4,693	10,302
TOTAL EQUITY AND LIABILITIES		108,977	92,055	102,095

NOTE 1 - Selling and administrative expenses

	Jul-Sept	Jul-Sept	Jan-Sept	Jan-Sept	Full Year
KSEK	2019	2018	2019	2018	2018
Salaries	3,263	1,885	8,984	5,397	10,939
Office expenses	164	147	476	422	577
Consultants	1,999	891	6,896	4,811	7,388
Travelling expenses	187	117	699	502	798
Marketing expenses	326	117	926	405	812
Depreciation	97	97	292	292	389
Other expenses	278	77	1,188	173	743
Total selling and administrative expenses	6,314	3,331	19,461	12,002	21,646

