SENZA GEN Year-end report JANUARY-DECEMBER 2020

SenzaGen's sales tripled for the full year

Looking back on 2020, I am pleased to report that SenzaGen's progress on commercialization has had a positive impact and we are in a much better position today than we were a year ago. Despite the challenges posed by the ongoing pandemic, we succeeded in establishing our GARD® technology with new, international customers and tripling our sales from the previous year. In 2021, we will continue working toward our profitability target by approaching customers and industries that stand to benefit from the GARD® test's high predictivity and are interested in the additional skin toxicology services that we will be able to offer through our own now GLP-certified lab."



Axel Sjöblad, CEO

Full year 1 January-31 December

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- » Net sales totaled SEK 7,958 (2,724) thousand.
- » The operating loss was SEK -27,098 (-37,927) thousand.
- » Earnings per share were SEK -1.27 (-3.11).
- » Cash and cash equivalents at 31 December amounted to SEK 89,343 (120,467) thousand.
- » The board proposes that no dividend be paid to the Company's shareholders.

Significant events after the end of the year

» The Company's global collaboration agreement with Charles River Laboratories was renewed and expanded.

Second half year 1 July-31 December

- » Net sales totaled SEK 4,128 (1,072) thousand.
- » The operating loss was SEK -14,169 (-22,730) thousand.
- » Earnings per share were SEK -0.67 (-2.10).

Significant events during the second half year

- » Pharmaceuticals company H. Lundbeck A/S ordered GARD[®]skin and GARD[®]air tests for SEK 0.4 million.
- » The global medical device company Sonova placed an SEK 0.6 m order after evaluation.
- » A major US chemicals company ordered GARD[®]skin and GARD[®]potency tests for SEK 0.4 million.
- » SenzaGen signed a distribution agreement with Danske Teknologisk Institut (DTI) in Denmark.
- » The ESAC's scientific evaluation of GARD[®] was underway during the year. Their opinion was delayed until 2021 as a result of the COVID-19 pandemic.

Message from the CEO

Looking back on 2020, I am pleased to report that SenzaGen's progress on commercialization has had a positive impact and we are in a much better position today than we were a year ago. Despite the challenges posed by the ongoing pandemic, we succeeded in establishing our GARD® technology with new, international customers and tripling our sales from the previous year.

Performance for the year

In a challenging business climate, in which we could not reach the number of customers initially planned despite a rapid transition to digital channels, and in which the order and procurement processes of potential customers became much longer, our sales for the full year reached nearly SEK 8 million. This is both triple the sales we reported for the previous year and a figure that could have been even higher under normal circumstances. Given that we implemented restructuring and streamlining measures already at the beginning of the year and cut our costs because of the pandemic, we also achieved this sales figure with a significantly leaner organisation than we had in the previous year.

Updated, targeted and segment-specific communications about GARD® paved the way for several new companies to trial and evaluate our tests in the fall, including a major US chemicals company, pharmaceuticals company H. Lundbeck A/S and medical device company Sonova. These customer projects demonstrate that our direct contacts with international companies deliver the desired results, and we have performed tests in 2020 for companies in all the major industries we cater to – pharmaceuticals, medical devices, cosmetics and chemicals.

Strategic transition

We worked on seven strategic initiatives during the year centered around how, as a company, we can be more agile, customer-focused and responsive to the challenges in each of our customer segments. I will briefly comment on the highlights of our progress on these initiatives:

Understand and prioritize customers' needs and Adapt our business model

To establish the GARD® technology and grow as a company, we improved our knowledge of needs in the industries we prioritize by engaging in several discussions with companies. This led to a more detailed market segmentation and an updated value proposition. In parallel with these marketing efforts, we also strengthened our business model both by adding new distribution partners and by increasing capacity in our own lab. Furthermore, we decided to respond to customer demand for a broader range of services by adding already existing skin toxicology tests with other endpoints that complement our GARD® offering.

Build strategic partnerships and Adapt and develop our product portfolio

Strategic partnerships play an absolutely crucial role for our sales and market presence. During the year, we continued working on stepping up collaboration with our existing distributors, most recently, after the end of the reporting period, with a renewed and expanded collaboration agreement with Charles River, one of the world leaders in laboratory services. We also worked on broadening our partner network during the year, focusing on key ambassadors for alternative testing methods including Danske Teknologisk Institut, which has a large network of global customers, leading research institutes and higher education institutions.

Our partners help us not only with marketing and sales but also contribute to work on developing our product portfolio. By developing and adapting new unique applications, such as a 100% vegan test for contract lab XCellR8 in the UK and a photosensitization test in collaboration with the US Research Institute for Fragrance Materials (RIFM), we have created additional offerings that meet market needs.

In addition, we presented our new GARD® Dose-Response test at digital industry events in both Europe and the US in the fall. The test, which is the first of its kind and provides information on the dosage at which a substance causes allergy, further solidifies SenzaGen's position on the cutting edge of skin toxicology. This new capability to quantify allergenicity has attracted great interest and is now being evaluated by several customers.

Ensure capabilities and sufficient resources and Adapt internal processes, systems and tools The COVID-19 pandemic has hindered us from building our sales organization according to my original plan, but the recruitment of two new key account managers, one based in France and one in Sweden, nevertheless strengthens our presence in the key European market. In addition, increased direct sales increased the importance of our own lab. Therefore, we have also recruited a new, highly experienced VP Operations whose main task is to scale up and secure our future testing capacity. The highlights of our progress on the process initiative include the implementation of a new quality management system and the GLP certification of our laboratory, which is one of only two in Sweden in our niche.

Ensure regulatory acceptance

During the year, we continued to work to ensure local, international and industry-specific regulatory acceptance, and one of the year's greatest achievements was the aforementioned GLP certification of our lab. This certification means that we can now meet our customers' various quality and regulatory requirements for product filings while also serving as clear evidence that GARD® can be used in a lab subject to regulatory monitoring, which is very positive both for our sales and for the ongoing OECD validation of GARD®skin and GARD®potency.

In the medical devices segment, we continued working on the inclusion of GARD® in the annex for the update of the new ISO standard. This is expected to be complete in 2021. We also filed a Medical Device Development Tools (MDDT) submission with the American FDA for GARD®skin Medical Device. The aim of the submission is for the FDA to qualify GARD® as a test for use in the development and evaluation of medical devices.

In November, we were informed by EURL ECVAM that its scientific advisory committee ESAC's scheduled fall meeting had been postponed to March 2021 due to the pandemic. Given that we had productive and fruitful virtual meetings with members of ESAC's working group and EURL ECVAM during the year, it was disappointing that COVID-19 delayed ESAC's opinion on GARD®, but I understand their decision considering the circumstances. Looking forward, the delay means that, as previously announced, we will have to wait for the OECD's possible issuance of GARD® as a test guideline but we will be able to refer to the ESAC's opinion during the year.

2021 strategic initiatives

We will continue our transition from a research company to a commercial enterprise, and our plans for 2021 are based on continuing to strengthen our market presence and develop our organization. In marketing, we will focus on four initiatives: drive GARD® revenue growth, broaden our portfolio by adding new tests, building strategic partnerships, and continuing our efforts to meet regulatory requirements relevant to our customers. On the organization front, we will strengthen our resources, skills and processes to drive sales and increase testing capacity in our own lab.

Looking ahead

I am proud of the hard work of our employees, the strategic changes we have made during a turbulent and challenging time, and the sales increase we achieved as a result of our increased focus on commercialization. In 2021, we will continue working toward our profitability target by approaching customers and industries that stand to benefit from the GARD® test's high predictivity without requiring OECD validation and are interested in the additional skin toxicology services that we will be able to offer through our own now GLP-certified lab. With 2020 behind us, we are ready to scale up as soon as the pandemic's short-term consequences are out of the way, and I look forward to 2021 with confidence.

Axel Sjöblad, CEO

SenzaGen at a glance

Business concept

SenzaGen develops, performs and sells state-ofthe-art non-animal tests for assessing a substance's allergenicity. The GARD® test method combines genomic data from human cells with machine learning for a unique capability to assess whether a chemical could cause allergic reactions on the skin or in the respiratory tract. With excellent predictivity, GARD® meets needs in several industries and helps companies develop, produce and deliver safer, ethical and more sustainable products.

Our contribution

SenzaGen's tests contribute to safer, ethical and more sustainable products while also drastically reducing the number of animal tests.

Vision

SenzaGen's vision is to replace animal testing with best-in-class *in vitro* technology, establish a new industry standard and contribute to safer products in society.

Mission

SenzaGen's mission is to develop and offer the best alternatives to animal tests.

A market with great potential

The skin-related *in vitro* toxicology testing market is global, and SenzaGen estimates its current addressable market at approximately SEK 5 billion. The majority of the Company's sales are made from its headquarters in Lund supplemented by partner sales. All product development operations are conducted in Lund.

Financial target and strategy

SenzaGen's financial target is to reach breakeven by 2022. To achieve this target, SenzaGen has established the following strategic initiatives:

Increase our market presence

- Drive GARD[®] revenue growth
- Broaden our portfolio
- Build strategic partnerships
- Ensure regulatory acceptance

Build a world-class organization

- Ensure the right capabilities and resources
- Optimize and adapt internal processes, systems and tools

The GARD[®] technology

SenzaGen's GARD[®] technology platform replaces animal testing with human cells in test tubes combined with machine learning and artificial intelligence.

Scientific studies show that SenzaGen's test method is significantly more reliable than the other methods on the market. By analyzing hundreds of markers, GARD[®] generates large quantities of data and delivers results with up to 94% accuracy.

Glossary

allergies.

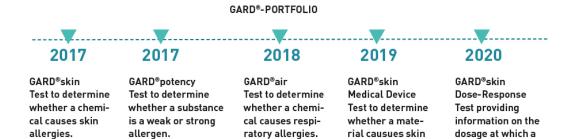
EURL ECVAM: European Union Reference Laboratory for alternatives to animal testing.

ESAC: The EURL ECVAM Scientific Advisory Committee. *In vitro*: Latin for "in glass". *In vitro* tests are done in test tubes.

In vivo: Latin for "in a living organism". *In vivo* tests are done on animals.

chemical causes

allergy.



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Sales, earnings and investments

Full year

Consolidated net sales for full year 2020 amounted to SEK 7,958 (2,724) thousand.

The consolidated operating loss was SEK -27,098 (-37,927) thousand.

Operating expenses for the year totaled SEK 35,305 (44,693) thousand. The decrease in operating expenses is largely due to the restructuring of the organization.

SenzaGen capitalizes new development expenditure and recognizes patents in the balance sheet on an ongoing basis. Total investments in intangible assets for the year were SEK 2,425 (2,915) thousand, with patents and trademarks accounting for SEK 2,091 (1,805) thousand of this amount. Capitalized expenditure for in-house development projects totaled SEK 334 (2,192) thousand. In 2019, a direct-write down of development expenditure amounting to SEK 1,082 thousand was recognized due to EU grants. In the second half of 2020, the Company recognized an SEK 508 thousand impairment loss on a development project that was charged to profit or loss.

Second half year

Consolidated net sales for the period amounted to SEK 4,128 (1,072) thousand.

The consolidated operating loss was SEK -14,169 (-22,730) thousand.

Operating expenses for the period totaled SEK 18,499 (24,158) thousand.

Funding

The Group's cash and cash equivalents at the end of the year totaled SEK 89,343 (120,467) thousand.

Net cash from operating activities for the year was SEK -29,376 (-31,095) thousand. Cash flow for the period was impacted by outlays due to restructuring, decreased trade payables, increased trade receivables and inventory accumulation.

Total net cash flow for the year amounted to SEK -31,124 (63,835) thousand.

During the year, 217,500 stock options were granted under the incentive programs for the employees and board adopted by the extraordinary general meeting in December 2019.

The 2020 Annual General Meeting resolved to authorize the board to resolve to issue new shares, of which the combined total results in no more than a 20% increase in share capital based on the total share capital at the time of the 2020 Annual General Meeting.

Parent Company

The Parent Company's net sales for the January– December 2020 period totaled SEK 7,958 (2,724) thousand. The loss before tax was SEK -27,257 (-37,842) thousand.

The Parent Company's net investments in both property, plant and equipment and intangible assets for the year amounted to SEK 2,425 (3,611) thousand, and its total cash flow was SEK -31,043 (63,559) thousand.

For further information, see the disclosures for the Group.

Otherinformation

Group consolidation

SenzaGen AB (publ) (reg. no. 556821-9207), based in Lund, is the parent company of subsidiary SenzaGen North America Inc, based in North Carolina, USA (reg. no. C3870650).

Accounting policies

The accounting policies applied are in compliance with the Swedish Annual Accounts Act (1995:1554) and the general advice of the Swedish Accounting Standards Board in BFNAR 2012:1 Annual Reports and Consolidated Financial Statements ("K3"). The same accounting policies and calculation bases were applied as those in 2019 Annual Report.

All operating activities are currently conducted by the parent company. As a result, the consolidated financial statements and the parent company financial statements are basically identical.

The income statement presentation method was changed on 1 January 2020 from the nature of expense method to the function of expense method given the business's development from a research company to a commercial enterprise. Therefore, the comparative figures have been restated using the function of expense method for the Group and the Parent Company. As a result of the use of the function of expense method for presentation of the income statement, own work capitalized is now included in the total for research and development expenditure instead of being recognized as its own line item under the Operating income heading.

Information about risks and uncertainties

SenzaGen's business is exposed to several risks, including both operational and financial risks. The operational risks mainly comprise uncertainty concerning product development, supplier agreements, product liability and distribution. For a more detailed description of the risks and uncertainties to which SenzaGen is exposed, see the risk and sensitivity analysis in the 2019 Annual Report.

Research and development

SenzaGen conducts research projects to strengthen its product portfolio. The Company's product development is based on the GARD[®] technology platform, which is robust, functional and has potential in a wide variety of toxicology applications and market segments.

Employees

At the end of the period, the Company had 17 (23) employees, 10 (15) of which were women and 7 (8) were men.

Significant events after the end of the year

On 22 January, SenzaGen announced that the Company had renewed and expanded its global collaboration agreement with contract research organization Charles River Laboratories, one of the world leaders in laboratory services. To meet the growing interest in chemical risk assessment with SenzaGen's non-animal test platform GARD®, their collaboration was broadened to now include sales of all tests in the GARD® portfolio. This collaboration has been ongoing since 2017.

Proposed dividend

The board proposes that no dividend be paid to the Company's shareholders.

Audit

This report was not reviewed by the Company's auditors.

2021 AGM

SenzaGen's 2021 Annual General Meeting (AGM) will be held on 5 May at 4 PM in Medicon Village's conference rooms at Scheelevägen 2, Lund.

Shareholders who wish to have an item deliberated on at the AGM may send a written request by email to <u>ir@senzagen.com</u> or by regular mail to: Styrelsen, SenzaGen AB, Medicon Village, 223 81 Lund. Such requests must be received no later than seven weeks prior to the AGM to be eligible for inclusion in the meeting notice and, consequently, the AGM agenda. Certified Adviser FNCA Sweden AB is the Company's Certified Adviser on Nasdaq First North. Phone: +46 8-528 00 399 | <u>info@fnca.se</u>

Financial calendar

2020 Annual Reportweek 12 2021AGM5 May 2021January-June 2021 Interim Report19 August 2021

Interim reports and annual reports are available on SenzaGen's website.

The board of directors and CEO assure that the interim report provides a true and fair view of the Parent Company and Group's business, financial position and financial performance and discloses significant risks and uncertainties to which the Parent Company and Group companies are exposed.

Lund, 18 February 2021

Carl Borrebaeck *Chairman* Laura Chirica *Director* Anki Malmborg Hager *Director*

lan Kimber *Director* Peter Nählstedt *Director*

Paula Zeilon *Director*

Axel Sjöblad *CEO* Paul Yianni *Director*

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Publication

This information constitutes the type of information SenzaGen AB is required to publish under the EU Market Abuse Regulation. This information was released for publication by the contact person set out above on 18 February 2021 at 08:30 AM CET.

Address

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SenzaGen is listed on Nasdaq First North. The Company is traded under the ticker symbol SENZA and ISIN code SE0010219626.

Condensed consolidated statement of comprehensive income	Jul-Dec	Jul-Dec	Full year	Full year
(SEK thousand)	2020	2019	2020	2019
Operating income				
Net sales	4,128	1,072	7,958	2,724
Cost of goods sold	-1,375	-632	-2,380	-1,416
Gross profit/loss	2,753	440	5,578	1,308
Selling expenses	-10,703	-9,281	-20,841	-16,627
Administrative expenses	-3,736	-9,278	-8,357	-18,212
Research and development expenditure	-1,657	-4,902	-2,626	-8,335
Other operating income	202	356	249	4,042
Other operating expenses*	-1,028	-65	-1,101	-103
Operating profit/loss	-14,169	-22,730	-27,098	-37,927
Profit/loss from financial items				
Interest income and similar items	35	185	76	185
Interest expenses and similar items	-146	-1	-146	-1
Profit/loss after financial items	-14,280	-22,546	-27,168	-37,743
Tax expenses	0	-12,494		-12,494
Profit/loss for the period	-14,280	-35,040	-27,168	-50,237
Share of profit/loss attributable to Parent Company shareholders	-14,280	-35,040	-27,168	-50,237

*The other operating expenses item includes an SEK 508 thousand impairment loss on a

development	project
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	Jul-Dec	Jul-Dec	Full year	Full year
Per share data	2020	2019	2020	2019
Earnings per share (SEK)	-0.67	-2.10	-1.27	-3.11
Fully diluted earnings per share (SEK)	-0.67	-2.10	-1.27	-3.11
Equity per share (SEK)	5.05	6.28	5.05	6.28
Equity ratio (%)	97%	94%	97%	94%
Number of outstanding shares at end of period (thousands)	21,358	21,358	21,358	21,358
Average number of outstanding shares (thousands)	21,358	16,673	21,358	16,176
Share price at end of period (SEK)	13.10	18.66	13.10	18.66

Definitions of financial ratios

Earnings per share.

Profit/loss for the period as a percentage of the weighted average number of shares.

Equity per share.

Equity as a percentage of the number of shares at the end of the period.

Equity ratio.

Equity as a percentage of total assets.

Condensed consolidated statement of financial			
position	31 Dec.	30 June	31 Dec.
(SEK thousand)	2020	2020	2019
Assets			
Intangible assets	15,367	16,476	16,079
Property, plant and equipment	2,097	2,696	3,273
Inventories	1,065	1,344	704
Trade receivables	1,521	1,888	205
Other receivables	2,155	1,837	2,232
Cash and cash equivalents	89,343	101,536	120,467
Total assets	111,548	125,777	142,960
Equity and liabilities			
Equity	107,792	122,018	134,211
Non-interest-bearing current liabilities	1,164	1,314	1,282
Trade payables	1,306	742	2,843
Restructuring provision	-	226	3,092
Other liabilities	1,286	1,477	1,532
Total equity and liabilities	111,548	125,777	142,960
Statement of changes in equity	31 Dec.	30 June	Full year
(SEK thousand)	2020	2020	2019
Opening balance	134,211	134,211	85,936
New share issues	-	-	105,958
New share issue expenses	-	-	-10,749
Effect of employee stock option plan	698	698	3,318
Profit/loss for the period	-27,168	-12,888	-50,237
Foreign currency effect	51	-3	-15
Equity at end of period	107,792	122,018	134,211

Condensed consolidated statement of cash flows	Jul-Dec	Jul-Dec	Full year	Full year
(SEK thousand)	2020	2019	2020	2019
Operating profit/loss after tax	-14,280	-35,040	-27,168	-50,237
Adjustments for non-cash items	2,502	14,193	4,385	15,469
Net cash from operating activities	-11,778	-20,847	-22,783	-34,768
before changes in working capital				
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Changes in working capital	325	6,293	-6,593	3,673
Net cash from operating activities	-11,453	-14,554	-29,376	-31,095
Acquisitions/disposals of intangible assets	-740	-1,478	-2,425	-2,915
Acquisitions/disposals of property, plant and equipment	-	-580	-21	-682
Net cash from investing activities	-740	-2,058	-2,446	-3,597
New share issue	-	105,958	-	105,958
Transaction expenses attributable to new share issue	-	-10,749	-	-10,749
Option premium	-	-	698	-
Option redemption	-	-	-	3,318
Net cash from financing activities	0	95,209	698	98,527
Total cash flow for the period	-12,193	78,597	-31,124	63,835
Cash and cash equivalents at start of period	101,536	41,870	120,467	56,632
Cash and cash equivalents at end of period	89,343	120,467	89,343	120,467
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Parent Company income statement	Jul-Dec	Jul-Dec	Full year	Full year
(SEK thousand)	2020	2019	2020	2019
Operating income				
Net sales	4,128	1,072	7,958	2,724
Cost of goods sold	-1,375	-632	-2,380	-1,416
Gross profit/loss	2,753	440	5,578	1,308
Selling expenses	-10,746	-9,367	-20,941	-16,740
Administrative expenses	-3,736	-9,273	-8,357	-18,212
Research and development expenditure	-1,657	-4,871	-2,626	-8,334
Other operating income	202	356	249	4,042
Other operating expenses*	-1,028	-65	-1,101	-103
Operating profit/loss	-14,212	-22,780	-27,198	-38,039
Profit/loss from financial items				
Interest income and similar items	46	198	87	198
Interest expenses and similar items	-146	-1	-146	-1
Profit/loss after financial items	-14,312	-22,583	-27,257	-37,842
Tax expenses	0	-12,494	-	-12,494
Profit/loss for the period	-14,312	-35,077	-27,257	-50,336

*The other operating expenses item includes an SEK 508 thousand impairment loss on a development project

Parent Company balance sheet	31 Dec.	30 June	31 Dec.
(SEK thousand)	2020	2020	2019
	2020	2020	2017
Assets			
Intangible assets	15,367	16,476	16,079
Property, plant and equipment	2,097	2,696	3,273
Financial assets	84	84	84
Inventories	1,065	1,344	704
Trade receivables	1,532	1,888	219
Receivables from Group companies	1,076	1,223	1,317
Other receivables	931	1,017	1,259
Prepaid expenses and accrued income	1,215	813	962
Cash and bank balances	88,961	101,229	120,005
Total assets	112,328	126,770	143,902
Equity and liabilities			
Equity	108,179	122,491	134,738
Non-interest-bearing current liabilities	1,164	1,314	1,282
Trade payables	1,699	1,262	3,258
Restructuring provision	-	226	3,092
Other liabilities	741	1,204	1,098
Accrued expenses and deferred income	545	273	434
Total equity and liabilities	112,328	126,770	143,902