

SenzaGen's sales doubled in the first half of 2020

“ Despite operating in a time when the ordering and purchasing processes of our customers have been significantly influenced by COVID-19, our sales increased in the first six months of 2020 to SEK 3.8 million, representing a more than double year-on-year increase and one million higher than our entire 2019 sales. With a focused sales organization and more potential customers evaluating our tests, we are in a great position to continue developing as a commercial enterprise despite the current external challenges. I believe that we have passed the test of transitioning to the "new normal" with flying colors and that we will be able to keep up the same fast pace when working on our strategic initiatives in the fall.”



Axel Sjöblad, CEO

Half year 1 January–30 June

- » Net sales totaled SEK 3,830 (1,652) thousand.
- » The operating loss was SEK -12,929 (-15,197) thousand.
- » Earnings per share were SEK -0.60 (-0.97).
- » Cash and cash equivalents at 30 June amounted to SEK 101,536 (41,870) thousand.

Significant events during the first half year

- » A new global customer ordered tests for a cumulative value of SEK 1.2 million.
- » SenzaGen received an order worth SEK 0.5 million from a world-leading raw material supplier.
- » SenzaGen received GLP approval.
- » SenzaGen and XCellR8 expanded their collaboration to offer GARD®skin Animal Product-Free.
- » SenzaGen and US Research Institute for Fragrance Materials (RIFM) signed a collaboration agreement to develop next-generation tests for photosensitization.

Significant events after the end of the period

- » SenzaGen signed a distribution agreement with Danske Teknologisk Institut (DTI) in Denmark.

Message from the CEO

After one year as CEO of SenzaGen, I am pleased to report that we have taken the first steps in transitioning from a research company to an enterprise with a strong commercial focus – a change that is clearly reflected in both our day-to-day work and in our sales growth for the first half of 2020.

Performance for the half year

Despite operating in a time when the ordering and purchasing processes of our customers have been significantly influenced by COVID-19, our sales increased in the first six months of 2020 to SEK 3.8 million, representing a more than double year-on-year increase and one million higher than our entire 2019 sales.

It is also highly positive that our customer base is growing in several segments and that existing customers are returning with new orders. A good example of this is when a new customer, a large global corporation, purchased chemical testing from us in February and then ordered more tests in the spring following the initial successful project.

Successful strategic transition

Since the start of the year, we have been pursuing an updated strategy based on seven strategic initiatives all 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 needed to better understand customers' needs in the industries we sell to: chemicals, cosmetics, medical devices and pharmaceuticals. Following a range of correspondence and conversations with customers and government agencies, we made our segmentation more detailed and updated our value proposition. Our goal is to use this value proposition as a basis to communicate more specific and targeted information about GARD® so that more companies will try out and evaluate our tests. In parallel with these marketing efforts, we

have strengthened our business model both by adding new business partners and increasing the number of tests in our own lab.

Build strategic partnerships and Adapt and develop our product portfolio

Strategic partnerships play a crucial role for our sales and market presence. During the half year we stepped up collaboration with our distributors and further broadened our partner network. Danske Teknologisk Institut, which is very strong in several of the industries we prioritize, was the latest addition after the end of the reporting period.

Our partners help us not only with marketing and sales but also with efforts to develop our product portfolio. By developing and adapting new unique applications, such as those for contract lab XCellR8 and US Research Institute for Fragrance Materials (RIFM), we have ensured that our portfolio meets market needs.

In addition to the direct partnerships mentioned above, some of our customers and partners also evaluate new applications before we launch them globally. At a webinar in June, we pre-launched GARD®skin Dose-Response, a test that assesses the skin sensitizing potency of a chemical in a far more quantitative manner than GARD®potency. We had a record-high number of attendees and received highly valuable feedback. This is indicative of a great interest in and need for the test, which is the first of its kind globally.

Finally, our partners play an important part in building trust in GARD®. Both XCellR8 and RIFM are ambassadors for ethical and alternative test methods, and we are joining forces with them to drive the paradigm shift in the testing industry.

Ensure capabilities and sufficient resources and Adapt internal processes, systems, and tools

Unfortunately, the COVID-19 pandemic has hindered us from building our sales organization at the pace I hoped, but the recruitment of a new key account manager based in France has strengthened our presence in the key European market. A local market presence, the right experience and efficient working methods are key components of the team we are putting together.

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 a highly important milestone for increased market presence.

Ensure regulatory acceptance

We intensified our efforts to meet local and industry-specific regulatory requirements and initiated several new processes during the first half of the year. We 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 Europe, we continued working on the inclusion of GARD® in the update of the new ISO standard for medical devices, which is expected to be complete in 2021 and has progressed in a highly positive spirit.

The aforementioned GLP certification, which we received from SWEDAC in May, is also a key regulatory milestone that we are very pleased with. On the one hand, this certification means that we can meet our customers' various quality and regulatory requirements for product filings, and on the other, it serves as clear evidence that GARD® can be used in a lab subject to regulatory monitoring, which is very positive for the ongoing OECD validation.

In the OECD validation process, EURL ECVAM's Scientific Advisory Committee (ESAC) is currently conducting its evaluation. The next key step in the process is the expert group's report, which will serve as a scientific evaluation and provide a clear indication of the group's stance on the GARD® validation.

Impact of the COVID-19 pandemic

It is clear that our customers' buying patterns have changed and become longer as they have been conservative about new investments due to the uncertainty surrounding COVID-19. Nevertheless, we are in a much better position now than the same period last year because of the organizational changes we made and the sales focus we established.

In the spring, we significantly increased customer interactions and quickly and successfully transitioned from in-person meetings to digital platforms. We organized many very successful webinars and video conferences on a regular basis with significantly more attendees than before. Additionally, we secured inventories of critical products and put in place procedures to enable our lab staff to perform the increasing number of tests in demand from our customers.

Going forward

I am proud of the hard work of our employees and the strategic changes we have made during a turbulent and challenging time. With a focused sales organization and more potential customers evaluating our tests, we are in a great position to continue developing as a commercial enterprise despite the current external challenges. I believe that we have passed the test of transitioning to the "new normal" with flying colors and that we will be able to keep up the same fast pace when working on our strategic initiatives in the fall.

Axel Sjöblad, CEO

SenzaGen at a glance

Business concept

SenzaGen develops, performs and sells tests that assess the allergenicity of chemicals in various products. These tests replace animal testing with genomic data from human cells combined with machine learning and are more reliable than other tests. The Company thus meets market demand for ethical, reliable, and cost-effective test methods.

Our contribution

SenzaGen's test methods are faster, more cost-effective and more accurate than animal testing, ensuring safer products in people's everyday lives while reducing the number of animal tests.

Vision

SenzaGen's vision is to set a new global industry standard for *in vitro* toxicology testing and completely replace animal testing.

Mission

SenzaGen's mission is to develop best-in-class animal-free test methods that facilitate the development of safer products.

A market with great potential

The *in vitro* toxicology testing market is global, and SenzaGen estimates its addressable market at approximately SEK 5 billion. The Company's sales channels are its partners, its headquarters in Lund and its sales office in the US. All product development operations are conducted in Lund, where the lab also analyzes customer samples.

Financial target and strategy

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

- Understand and prioritize customers' needs
- Adapt and develop our product portfolio
- Build strategic partnerships
- Adapt our business model
- Ensure regulatory acceptance
- Ensure capabilities and sufficient resources
- Adapt internal processes, systems and tools

The GARD® technology

SenzaGen's GARD® technology platform replaces animal testing with genomic data from human cells combined with machine learning.

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 over 90% accuracy.

Glossary

In vitro: *In vitro* tests are done in test tubes.

GLP: Good Laboratory Practice

EURL: The European Union Reference Laboratory

ECVAM: European Centre for the Validation of Alternative Methods

ESAC: EURL ECVAM Scientific Advisory Committee

GARD PORTFOLIO, LAUNCH

2017

GARD™*skin*

Test to determine whether a chemical causes skin allergies.

2017

GARD™*potency*

Test to determine the extent to which a chemical causes skin allergies. Used in conjunction with GARD™*skin*.

2018

GARD™*air*

Test to determine whether a chemical causes respiratory allergies.

2019

GARD™*skin* Medical Device

Test to determine whether a material causes skin allergies.

Sales, earnings and investments

First half year

Consolidated net sales for the period totaled SEK 3,830 (1,652) thousand.

The consolidated operating loss was SEK -12,929 (-15,197) thousand.

Total operating expenses for the period amounted to SEK 16,169 (22,217) 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 period were SEK 1,685 (2,518) thousand, with patents and trademarks accounting for SEK 1,316 (836) thousand of this amount. Capitalized expenditure for in-house development projects totaled SEK 369 (1,682) thousand. In 2019, a direct-write down of development expenditure amounting to SEK 1,082 thousand was recognized due to EU grants.

Funding

The Group's cash and cash equivalents at the end of the period totaled SEK 101,536 (41,870) thousand.

Net cash from operating activities for the period was SEK -17,923 (-16,541) thousand.

Cash flow for the period was impacted by payment in respect of the restructuring provision, decreased trade payables, increased trade receivables and inventory accumulation.

Total net cash flow for the period amounted to SEK -18,931 (-14,762) thousand.

During the period, 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-June period totaled SEK 3,830 (1,652) thousand. The loss before tax was SEK -12,945 (-15,259) thousand.

The Parent Company's net investments in both property, plant and equipment and intangible assets for the year amounted to SEK 1,706 (1,539) thousand, and its total cash flow was SEK -18,775 (-14,873) thousand.

For further information, see the disclosures for the Group.

Other information

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).

Segment reporting

SenzaGen's business currently includes only one operating segment, allergen analysis. Therefore, see the income statement and balance sheet for operating segment reporting.

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 period

On 9 July, SenzaGen announced that the Company signed a distribution agreement with Danske Teknologisk Institut (DTI), a renowned research institute. DTI commands a strong position as an advocate of new technology with a large network of global customers, leading research institutes and higher education institutions. The agreement further broadens SenzaGen's network of licensees and distributors in Europe with the addition of a strategically important partner.

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.

Audit

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

Certified Adviser

FNCA Sweden AB is the Company's Certified Adviser on Nasdaq First North.

Financial calendar

2020 Year-End Report 18 February 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, 20 August 2020

Carl Borrebaeck
Chairman

Laura Chirica
Director

Anki Malmberg Hager
Director

Ian Kimber
Director

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Publication

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

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Condensed consolidated statement of comprehensive income (SEK thousand)	Jan-Jun 2020	Jan-Jun 2019	Full year 2019
Operating income			
Net sales	3,830	1,652	2,724
Cost of goods sold	-1,005	-784	-1,416
Gross profit/loss	2,825	868	1,308
Selling expenses	-10,138	-7,346	-16,627
Administrative expenses	-4,621	-8,934	-18,212
Research and development expenditure	-969	-3,433	-8,335
Other operating income	47	3,686	4,042
Other operating expenses	-73	-38	-103
Operating profit/loss	-12,929	-15,197	-37,927
Profit/loss from financial items			
Interest income and similar items	41	-	185
Interest expenses and similar items	-	-	-1
Profit/loss after financial items	-12,888	-15,197	-37,743
Tax expenses	-	-	-12,494
Profit/loss for the period	-12,888	-15,197	-50,237
Share of profit/loss attributable to Parent Company shareholders	-12,888	-15,197	-50,237

Per share data	Jan-Jun 2020	Jan-Jun 2019	Full year 2019
Earnings per share (SEK)	-0.60	-0.97	-3.11
Fully diluted earnings per share (SEK)	-0.60	-0.97	-3.11
Equity per share (SEK)	5.71	4.71	5.71
Equity ratio (%)	97%	93%	94%
Number of outstanding shares at end of period (thousands)	21,358	15,737	21,358
Average number of outstanding shares (thousands)	21,358	15,678	16,176
Share price at end of period (SEK)	16.90	30.55	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 (SEK thousand)	30 June 2020	30 June 2019	31 Dec. 2019
Assets			
Intangible assets	16,476	15,800	16,079
Property, plant and equipment	2,696	3,275	3,273
Deferred tax assets	-	12,494	-
Inventories	1,344	-	704
Trade receivables	1,888	678	205
Other receivables	1,837	5,297	2,232
Cash and cash equivalents	101,536	41,870	120,467
Total assets	125,777	79,414	142,960
Equity and liabilities			
Equity	122,018	74,124	134,211
Non-interest-bearing current liabilities	1,314	1,243	1,282
Trade payables	742	2,720	2,843
Restructuring provision	226	-	3,092
Other liabilities	1,477	1,327	1,532
Total equity and liabilities	125,777	79,414	142,960
Statement of changes in equity (SEK thousand)	30 June 2020	30 June 2019	31 Dec. 2019
Opening balance	134,211	85,936	85,936
New share issues	-	3,451	105,958
New share issue expenses	-	-	-10,749
Effect of employee stock option plan	698	-133	3,318
Profit/loss for the period	-12,888	-15,197	-50,237
Foreign currency effect	-3	67	-15
Equity at end of period	122,018	74,124	134,211

Condensed consolidated statement of cash flows (SEK thousand)	Jan-Jun 2020	Jan-Jun 2019	Full year 2019
Operating profit/loss after tax	-12,888	-15,197	-50,237
Adjustments for non-cash items	1,883	1,276	18,575
Net cash from operating activities before changes in working capital	-11,005	-13,921	-31,662
Changes in working capital	-6,918	-2,620	581
Net cash from operating activities	-17,923	-16,541	-31,081
Acquisitions/disposals of intangible assets	-1,685	-1,437	-2,915
Acquisitions/disposals of property, plant and equipment	-21	-102	-696
Net cash from investing activities	-1,706	-1,539	-3,611
New share issue	-	-	105,958
Transaction expenses attributable to new share issue	-	-	-10,749
Option premium	698	-133	-
Option redemption	-	3,451	3,318
Net cash from financing activities	698	3,318	98,527
Total cash flow for the period	-18,931	-14,762	63,835
Cash and cash equivalents at start of period	120,467	56,632	56,632
Cash and cash equivalents at end of period	101,536	41,870	120,467

Parent Company income statement (SEK thousand)	Jan-Jun 2020	Jan-Jun 2019	Full year 2019
Operating income			
Net sales	3,830	1,652	2,724
Cost of goods sold	-1,005	-784	-1,416
Gross profit/loss	2,825	868	1,308
Selling expenses	-10,195	-7,373	-16,740
Administrative expenses	-4,621	-8,939	-18,212
Research and development expenditure	-969	-3,463	-8,334
Other operating income	47	3,686	4,042
Other operating expenses	-73	-38	-103
Operating profit/loss	-12,986	-15,259	-38,039
Profit/loss from financial items			
Interest income and similar items	41	-	198
Interest expenses and similar items	-	-	-1
Profit/loss after financial items	-12,945	-15,259	-37,842
Tax expenses	-	-	-12,494
Profit/loss for the period	-12,945	-15,259	-50,336

Parent Company balance sheet (SEK thousand)	30 June 2020	30 June 2019	31 Dec. 2019
Assets			
Intangible assets	16,476	15,800	16,079
Property, plant and equipment	2,696	3,261	3,273
Deferred tax assets	-	12,494	-
Financial assets	84	84	84
Inventories	1,344	-	704
Trade receivables	1,888	678	219
Receivables from Group companies	1,223	1,218	1,317
Other receivables	1,017	1,069	1,259
Prepaid expenses and accrued income	813	4,216	962
Cash and bank balances	101,229	41,573	120,005
Total assets	126,770	80,393	143,902
Equity and liabilities			
Equity	122,491	74,606	134,738
Non-interest-bearing current liabilities	1,314	1,243	1,282
Trade payables	1,262	3,376	3,258
Restructuring provision	226	-	3,092
Other liabilities	1,204	949	1,098
Accrued expenses and deferred income	273	219	434
Total equity and liabilities	126,770	80,393	143,902