Half-yearly report

JANUARY-JUNE 2021

Positive ESAC opinion on GARD®skin and expanded range of tests open up new commercial opportunities

SenzaGen continues to enjoy strong commercial growth and achieved key successes as a company in the first six months of the year. Our innovative GARD® technology was validated by an independent group of international experts in the summer, making it the first genomic based test to achieve stand-alone status for identifying skin allergens. We broadened our lab operations in line with our strategy by adding more non-animal tests. This creates new opportunities for accelerated sales growth. I would like to thank my predecessor Axel Sjöblad for his excellent work as CEO that made these successes possible, thus creating a stable platform for continuing growth. We will further expand our lab operations in non-animal skin toxicology as soon as this fall, both by launching more tests and by pursuing supplementary mergers and acquisitions, which is a key part of our growth strategy."

Peter Nählstedt, CEO

Half year 1 January–30 June

- Net sales totaled SEK 5,015 (3,830) thousand.
- The operating loss was SEK -13,995 (-12,929) thousand.
- Earnings per share were SEK -0.65 (-0.60).
- Cash and cash equivalents at 30 June amounted to SEK 75,571 (101,536) thousand.

Significant events during the first half year

- Lab operations were broadened within *in vitro* skin toxicology.
- SenzaGen received an SEK 0.6 million GARD® order from a new European customer in the chemicals industry.
- Collaboration with RIFM on the safe use of fragrances with GARD®skin Dose-Response was expanded with an SEK 1.2 million grant.
- The global collaboration agreement with Charles River Laboratories was renewed and expanded.

Significant events after the end of the period

- Peter Nählstedt was appointed CEO.
- A very positive opinion on GARD®skin from ESAC experts paves the way for OECD validation.
- An SEK 0.65 million order for GARD®skin Dose-Response was secured from one of the world's largest cosmetics companies.
- An SEK 0.65 million order for skin allergy and irritation tests was received from a global consumer products company.

Message from the CEO

Over the past years, I have served on the Company's board and management team working on its strategy and commercial development. Given that I am well-acquainted with SenzaGen's amazing and highly motivated team, offering and potential.

SenzaGen continues to enjoy strong commercial growth and achieved key successes as a company in the first six months of the year. Our innovative GARD® technology was validated by an independent group of international experts in the summer, making it the first genomic based test to achieve stand-alone status for identifying positive skin allergens. We broadened our lab operations in line with our strategy by adding more non-animal tests. This creates new opportunities for accelerated sales growth.

The Company's strategy has evolved seeking to expand our operations to become the preferred supplier of a range of high-performance *in vitro* tests. We are seeking to do this by also targeting profitable and growing companies with complementary portfolios with which we can expand our business through mergers and acquisitions.

I am now very much looking forward to leading the Company into the next phase in which we will continue to commercialize the GARD® platform, add more tests to our portfolio and actively seek acquisition opportunities.

Performance for the half year
We continue to take market share and our sales are growing well. In a time when the ordering and purchasing processes of our customers and our ability to market our disruptive technology are still significantly impaired by COVID-19, our sales passed the SEK 5 million mark in the first half year. This represents a 31% year-on-year increase, beating the industry's average growth of about 10% per year by a wide margin.

Several major international companies that became SenzaGen customers in 2020 went on to continue using GARD® to determine whether, and at what dosage, their product candidates could cause allergy on the skin or in the respiratory tract. It is also highly positive that we have seen a substantial increase in inquires from new customers during the half year and after the end of the period. This increase in upcoming testing projects has prompted us to continue increasing the staff for our GLP-certified laboratory to meet customer timelines in the fall.

Our liquidity remains strong but we will continue to maintain good cost control practices until we see the impact of the pandemic decrease to such an extent that we regain full commercial opportunities.

Strategic initiatives
In the first half year, we further strengthened our market presence and organization while working to improve sustainability and ethics in the pre-clinical testing market. I will briefly comment on the highlights of our progress on our six strategic initiatives during the period:

Drive GARD® revenue growth
Targeted and segment-specific communications, often in collaboration with partners and key opinion leaders, enabled us to increase confidence in the GARD® technology, which led to several new customers trialing and evaluating our tests. Our new customers include a leading supplier of speciality chemicals, which tested substances that are difficult to assess for both skin and respiratory allergies for an order value of SEK 0.6 million, along with several companies offering products such as cosmetics, cleaning agents and hygiene items. This demonstrates that our commercial offering appeals to both new large companies and existing customers who continue to use GARD® after initial testing.

Additionally, our unique GARD®skin Dose-Response meets testing needs that industry has had for decades. Following an initial successful evaluation in the spring, the US Research Institute for Fragrance Materials (RIFM) decided to take the next step in a project in which our technology is used to define the dosage at which a fragrance becomes allergenic. Under a grant totalling SEK 1.2 million from RIFM, we are testing ingredients and contributing important information to their fragrance library. After the end of the reporting period, one of the largest companies in the world, a leader in beauty and cosmetics, also decided to test ingredients using the same test for an order value of SEK 0.65 million. This provides symbolic and highly important recognition for us and our technology in the cosmetics industry.

Broaden our offering
To address customer demand for a wider range of tests, we are gradually expanding our offering by adding non-animal tests in more skin toxicology domains. As of 1 July 2021, we also offer *in vitro* tests for skin irritation and corrosion to complement

our innovative GARD® platform. The fact that we have already received test orders for irritation is highly promising and a testament to our strategy and the feedback we received earlier.

Develop strategic partnerships
During the period, we continued working on stepping up collaboration with our existing distributors and broadening our partner network with a focus on ambassadors that are driving the transition to non-animal testing. Examples of this include an expanded collaboration agreement with Charles River, one of the world leaders in laboratory services, and a distribution agreement with US-based *in vitro* specialist Enthalpy.

Ensure regulatory acceptance
In July, we were informed by EURL ECVAM that their expert group ESAC had evaluated and issued a very positive opinion on GARD®skin. This good news, which we have waited a long time for, makes GARD®skin the first genomic based test to receive stand-alone status for positive sensitizers from EURL ECVAM, which recommends that the OECD add GARD®skin to their list of internationally approved skin sensitization test methods. With final OECD approval in place, we will be able to offer our tests to a broader group of customers in industries such as cosmetics and chemicals in the EU, US and Asia, which will pave the way for faster market growth. According to the information we have at this time, the OECD will be able to deliberate on GARD® at its annual meeting in April 2022. In the meantime, we are referring to the positive ESAC opinion in all of our contacts with customers and are already seeing a positive effect.

GARD®potency which was developed to differentiate strong from weak skin sensitizers has also been reviewed by ESAC. The approach was recognised as a functional and valid method, but further work is needed before it can be considered for regulatory approval. Assessment of the potency of skin sensitizing substances remains a high priority and in tandem with work on GARD®potency we have launched a complementary method, GARD®skin Dose-Response, to meet this need.

In the medical devices segment, we continued working on the inclusion of GARD® in the update of the ISO standard. This is expected to be completed and published in the latter part of 2021. Regarding our MDDT submission to the FDA for qualification of GARD® for risk assessment of medical devices in the US, we had a constructive dialogue with the FDA that moved the matter forward.

Ensure the right capabilities and resources
In terms of this initiative, we continue to boost our capabilities and increase our resources step-by-step in an aim to drive short-term sales and build a larger company with long-term viability. To increase capacity in our laboratory, we recruited two new employees during the period with experience from commercial labs.

Optimize and adapt internal processes, systems and tools
Our greatest progress in the process initiative is in sustainability. After completing a situation analysis, we created a code of conduct and several policies that now guide us in our efforts to ensure corporate social responsibility (CSR) and ethical conduct. The initiative also gives us a solid foundation for meeting our customers' high sustainability requirements in the supply chain.

Looking ahead

The positive ESAC opinion on GARD®skin paves the way for OECD approval and faster sales increases at the same time as our broadened range of tests opens up possibilities for new revenue streams. Although our revenue has been and still is impacted by the COVID-19 pandemic in the short term, which makes it especially important for us to maintain good cost control practices, we are sticking to our financial target of reaching profitability in 2022. We will further expand our lab operations in non-animal skin toxicology as soon as this fall, both by launching more tests and by pursuing supplementary mergers and acquisitions, which is a key part of our growth strategy. The goal of all this is to become a complete supplier of advanced, high-performance *in vitro* tests in our field.

Peter Nählstedt, CEO

SenzaGen at a glance

Business concept
SenzaGen develops, performs and sells state-of-the-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:

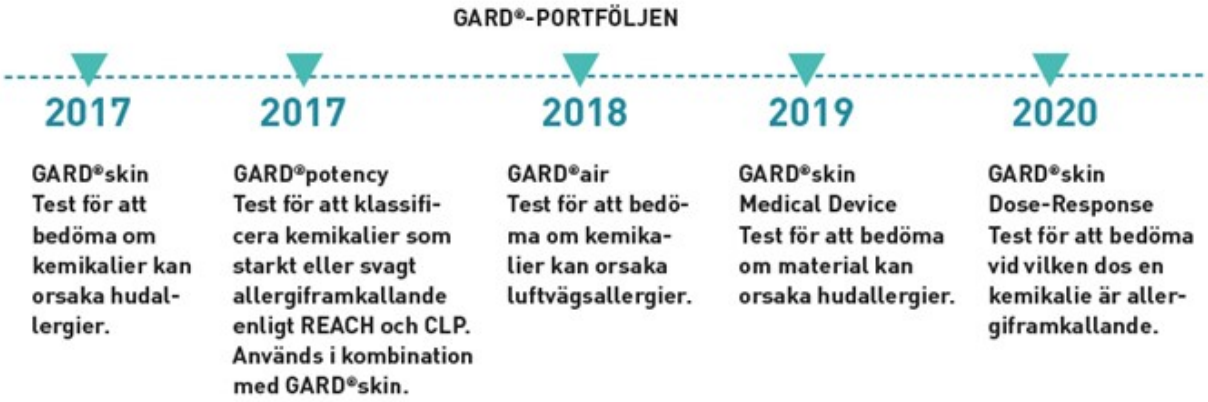
Increase our market presence
- Drive GARD® revenue growth
- Broaden our offering
- Develop strategic partnerships
- Ensure regulatory acceptance
- Grow with strategic mergers and acquisitions

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
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.
MDDT: Medical Device Development Tools.



Sales, earnings and investments

First half year
Consolidated net sales for the period amounted to SEK 5,015 (3,830) thousand.

The consolidated operating loss was SEK -13,995 (-12,929) thousand.

Operating expenses for the period totaled SEK 17,171 (16,169) thousand.

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 763 (1,685) thousand, with patents and trademarks accounting for SEK 732 (1,316) thousand of this amount. Capitalized expenditure for in-house development projects totaled SEK 31 (369) thousand.

Funding

The Group's cash and cash equivalents at the end of the period totaled SEK 75,571 (101,536) thousand.

Net cash from operating activities for the period was SEK -12,921 (-17,923) thousand.

Total net cash flow for the period amounted to SEK -13,772 (-18,931) thousand.

During the period, 25,000 stock options were subscribed and paid for under the incentive program for the board adopted by the extraordinary general meeting in December 2019.

During the period, 372,000 stock options were subscribed for by employees under the incentive program adopted by the 2021 Annual General Meeting.

The 2021 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 2021 Annual General Meeting.

Parent Company

The Parent Company's net sales for the January–June period totaled SEK 5,015 (3,830) thousand. The loss before tax was SEK -13,945 (-12,945) thousand.

The Parent Company's net investments in both property, plant and equipment and intangible assets for the year amounted to SEK 859 (1,706) thousand, and its total cash flow was SEK -13,803 (-18,775) 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.

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 the 2020 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.

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 2020 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 19 (17) employees, 10 (10) of which were women and 9 (7) were men.

Significant events after the end of the period
On 12 July, SenzaGen was selected to test ingredients in cosmetics products from one of the largest cosmetics companies in the world. The order is valued at SEK 0.65 million and is for the Company's GARD®skin Dose-Response test.

On 26 July, SenzaGen announced that EURL ECVAM reported that ESAC, its scientific committee, had issued a positive opinion on the GARD®skin test method. Depending on the regulatory context, ESAC finds that GARD®skin can be used on a stand-alone basis in the event of positive results and recommends that the OECD adopt the method as a test guideline for skin sensitization. This opinion is a key milestone in the process of obtaining regulatory approval for GARD®, which opens up new commercial opportunities for the Company.

On 6 August, a leading global consumer products company awarded SenzaGen a project to test product candidates in the product development phase. The order is valued at SEK 0.65 million and involves non-animal tests for both skin sensitization and skin irritation. This project is a testament to the feedback the Company received from earlier customers and the Company's strategy to broaden its lab operations with a wider range of non-animal skin toxicology tests.

On 18 August SenzaGen announced that the Board had appointed Peter Nählstedt as new CEO. Peter Nählstedt has extensive experience in developing global growth companies in Life Science. He was appointed to SenzaGens board of directors in 2018 and has during this time also worked operatively in the company with its commercial development. He has in recent years lead several international growth projects in Life Sciences as a consultant and a board professional. His most recent operative assignment was as CEO of Probi AB. During his time as CEO of Probi from 2014 to 2018, the company increased its revenues from 103 to 612 MSEK by combining organic international growth with acquisition activities. Prior to working for Probi, Peter has held leading positions at Trelleborg AB and GE Healthcare in Sweden and US. He holds an MSc in Chemical Engineering and a BSc in Business Administration from Lund University.

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

Certified Adviser
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Financial calendar
2021 Year-End Report 11 February 2022

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, 19 August 2021

Carl Borrebaeck *Chairman*	Laura Chirica *Director*	Anki Malmborg Hager *Director*
Ian Kimber *Director*	Peter Nählstedt *Director*	Paul Yianni *Director*
Paula Zeilon *Director*	Peter Nählstedt *CEO*	

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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 (SEK thousand)	Jan-Jun 2021	Jan-Jun 2020	Full year 2020
Operating income			
Net sales	5,015	3,830	7,958
Cost of goods sold	-2,092	-1,005	-2,380
Gross profit/loss	**2,923**	**2,825**	**5,578**
Selling expenses	-10,045	-10,138	-20,841
Administrative expenses	-5,658	-4,621	-8,357
Research and development expenditure	-1,261	-969	-2,626
Other operating income	221	47	249
Other operating expenses	-175	-73	-1,101
Operating profit/loss	**13,995**	**-12,929**	**-27,098**
Profit/loss from financial items			
Interest income and similar items	97	41	76
Interest expenses and similar items	-2	-	-146
Profit/loss after financial items	**-13,900**	**-12,888**	**-27,168**
Tax expenses	-	-	-
Profit/loss for the period	**-13,900**	**-12,888**	**-27,168**
Share of profit/loss to Parent Company shareholders	**-13,900**	**-12,888**	**-27,168**

Per share data	Jan-Jun 2021	Jan-Jun 2020	Full year 2020
Earnings per share (SEK)	-0,65	-0,60	-1,27
Fully diluted earnings per share (SEK)	-0,65	-0,60	-1,27
Equity per share (SEK)	4,40	5,71	5,05
Equity ratio (%)	96%	97%	97%
Number of outstanding shares at end of period (thousands)	21,358	21,358	21,358
Average number of outstanding shares (thousands)	21,358	21,358	21,358
Share price at end of period (SEK)	18,50	16,90	13,10

Definitions of financial ratios

Earnings per share

Profit/loss for the period as a percentage of 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 2021	30 June 2020	31 Dec 2020
Assets			
Intangible assets	14,741	16,476	15,367
Property, plant and equipment	1,669	2,696	2,097
Inventories	1,284	1,344	1,065
Trade receivables	1,795	1,888	1,521
Other receivables	2,783	1,837	2,155
Cash and cash equivalents	75,571	101,536	89,343
Total assets	**97,843**	**125,777**	**111,548**
Equity and liabilities			
Equity	93,874	122,018	107,792
Non-interest-bearing current liabilities	1,465	1,314	1,164
Trade payables	686	742	1,306
Restructuring provision	-	226	-
Other liabilities	1,818	1,477	1,286
Total equity and liabilities	**97,843**	**125,777**	**111,548**

Statement of changes in equity (SEK thousand)	30 June 2021	30 June 2020	31 Dec 2020
Opening balance	107,792	134,211	134,211
Effect of employee stock option plan	8	698	698
Profit/loss for the period	-13,900	-12,888	-27,168
Foreign currency effect	-26	-3	51
Equity at end of period	**93,874**	**122,018**	**107,792**

Condensed consolidated statement of cash flows (SEK thousand)	Jan-Jun 2021	Jan-Jun 2020	Full year 2020
Operating profit/loss after tax	**-13,900**	**-12,888**	**-27,168**
Adjustments for non-cash items	1,887	1,883	4,385
Net cash from operating activities before changes in working capital	**-12,013**	**-11,005**	**-22,783**
Changes in working capital	-908	-6,918	-6,593
Net cash from operating activities	**-12,921**	**-17,923**	**-29,376**
Acquisitions/disposals of intangible assets	-763	-1,685	-2,425
Acquisitions/disposals of property, plant and equipment	-96	-21	-21
Net cash from investing activities	**-859**	**-1,706**	**-2,446**
Option premium	8	698	698
Net cash from financing activities	**8**	**698**	**698**
Total cash flow for the period	**-13,772**	**-18,931**	**-31,124**
Cash and cash equivalents at start of period	89,343	120,467	120,467
Cash and cash equivalents at end of period	**75,571**	**101,536**	**89,343**

Parent Company income statement (SEK thousand)	Jan-Jun 2021	Jan-Jun 2020	Full year 2020
Operating income			
Net sales	5,015	3,830	7,958
Cost of goods sold	-2,092	-1,005	-2,380
Gross profit/loss	**2,923**	**2,825**	**5,578**
Selling expenses	-10,090	-10,195	-20,941
Administrative expenses	-5,658	-4,621	-8,357
Research and development expenditure	-1,261	-969	-2,626
Other operating income	221	47	249
Other operating expenses	-175	-73	-1,101
Operating profit/loss	**-14,040**	**-12,986**	**-27,198**
Profit/loss from financial items			
Interest income and similar items	97	41	87
Interest expenses and similar items	-2	-	-146
Profit/loss after financial items	**-13,945**	**-12,945**	**-27,257**
Tax expenses	-	-	-
Profit/loss for the period	**-13,945**	**-12,945**	**-27,257**

Parent Company balance sheet (SEK thousand)	30 June 2021	30 June 2020	31 Dec 2020
Assets			
Intangible assets	14,741	16,476	15,367
Property, plant and quipment	1,669	2,696	2,097
Financial assets	84	84	84
Intentories	1,284	1,344	1,065
Trade receivables	1,795	1,888	1,532
Receivables from Group companies	1,021	1,223	1,076
Other receivables	1,458	1,017	931
Prepaid expenses and accrued income	1,324	813	1,215
Cash and bank balances	75,158	101,229	88,961
Total assets	**98,534**	**126,770**	**112,328**
Equity and liabilities			
Equity	94,243	122,491	108,179
Non-interest-bearing current liabilities	1,465	1,314	1,164
Trade payables	1,008	1,262	1,699
Restructuring provision	-	226	-
Other liabilities	1,216	1,204	741
Accrued expenses and deferred income	602	273	545
Total equity and liabilities	**98,534**	**126,770**	**112,328**