SENZAGEN ANNUAL REPORT

2021

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

Contents

About **SenzaGen**

Business concept

SenzaGen aims to be a leader in *in vitro* science and testing, driving the transition from animal testing to methods better suited to reflect human biology. The Company provides high-performance, non-animal test methods and innovation and advisory services based on the latest technology. Non-animal methods are more effective, more accurate and less expensive than traditional animal-based methods while also helping to reduce the number of laboratory animals.

Growth strategy

SenzaGen's growth strategy combines organic growth with acquisition activities and can be summarized as follows:

- Continued commercialization of proprietary test platforms GARD® and ORA®.
- Expansion of test portfolio.
- Active acquisition agenda with a focus on profitable and growing companies with complementary offerings.

A market with great potential

The *in vitro* toxicology testing market is global and growing strongly. SenzaGen estimates its addressable market at approximately SEK 30 billion. The majority of the Company's sales are direct sales supplemented by sales via distributors and license partners.

Innovative *in vitro* offering

SenzaGen became an operating company in 2014. Prior to its founding, the EU had decided to no longer allow sales of cosmetic products tested on animals. This ban then spread to other countries and there are also processes in other industries in which there is an aim to avoid animal testing. Since then, the Company's innovative GARD® test platform, based on genomics and machine learning, has been developed to determine whether substances can cause allergic reactions, and more complementary tests and services have been added, most recently via VitroScreen, the recently acquired company with vast expertise in 3D models built using human cells.

Market segments for SenzaGen's tests and services

Cosmetics

Chemicals

Medical devices

Pharmaceuticals

Vision

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

OUR NON-ANIMAL OFFERING

Innovative patented tests

- GARD® platform
- ORA® platform

GLP regulatory toxicology testing

Pre-clinical testing

Innovation and advisory services

Our contribution to a more sustainable world

SenzaGen's non-animal tests and services help product development companies in several industries to provide significantly safer products and create better production environments for their employees while drastically decreasing the number of animal tests.

The year at a glance

- Peter Nählstedt was appointed the new CEO.
- New growth strategy combining organic growth with acquisition activities.
- The ESAC issued a highly positive opinion on GARD®skin.
- GARD® was incorporated into the annex of the new ISO standard for medical devices.
- The regulatory portfolio was broadened with tests for skin irritation and corrosion.
- Collaboration with the US Research Institute for Fragrance Materials (RIFM) was expanded with an SEK 1.2 million grant.
- The distribution agreement with Charles River Laboratories was renewed and expanded.
- One of the largest cosmetics companies in the world became a new customer and tested ingredients with GARD®skin Dose-Response for a cumulative value of SEK 1.65 million.
- One of the largest pharmaceuticals companies in the world became a new customer with an order for GARD®skin totaling SEK 0.7 million.
- A new global consumer products customer ordered skin allergy and irritation tests for SEK 0.65 million.
- A new European customer in the chemicals industry tested chemicals with GARD®skin and GARD®air for a value of SEK 0.6 million.
- SEK 30 million in capital was raised with a directed share issue.
- SenzaGen acquired Italy-based VitroScreen, which is active in preclinical testing and innovation.

FINANCIAL SUMMARY

SEK million	2021	2020	2019	2018
Net sales	15.4	8.0	2.7	2.0
Operating loss	-31.5	-27.1	-37.9	-20.7
Equity	110.2	107.8	134.2	85.9
Equity ratio (%)	82	97	94	95

GROWING CUSTOMER BASE

In 2021, interest in GARD® increased from major global corporations in several industries. Existing customers returned and placed follow-on orders while the customer base grew with new customer acquisitions. The new customers included one of the largest pharmaceuticals companies in the world and one of the largest cosmetics companies in the world.

REGULATORY PROGRESS

EURL ECVAM and its Scientific Advisory Committee (ESAC) recommended that the OECD approve GARD®skin as a test method for skin sensitization, paving the way for final OECD validation. GARD® was incorporated into the annex of the new ISO standard for medical devices.

VITROSCREEN ACQUISITION

The acquisition of VitroScreen broadened SenzaGen's offering to reach a significantly larger market.

The Company's offering now comprises a unique combination of non-animal services, including tests and advice in regulatory toxicology and preclinical efficacy along with innovation services for product development in industries such as pharmaceuticals and cosmetics. VitroScreen has vast expertise in human 3D tissue and organoid models, which enables advanced studies of drug efficacy and toxicological impact.

CEO's COMMENTS

Strong year for SenzaGen – sales nearly doubled, acquisition and new accelerated growth plan

In light of the Company's positive performance in 2021, SenzaGen is poised for a strong commercial future: sales are increasing, our customer base is growing and the VitroScreen acquisition has improved our offering and our market presence."

SenzaGen is in an exciting phase with great prospects for continued business success and expansion. Implementation of a new growth strategy with an active acquisition agenda has commenced, which sets both organic and acquisition-driven growth as goals for the Group. The strategy is clear and our sights are set high – we are already seeing very positive results from the investment.

I've now been wearing the CEO hat since late summer 2021, but I've been with the team for a couple years as both a director and a business developer. It gives me great satisfaction to see that our accelerated growth strategy, which was launched in August 2021, is already starting to deliver results and open up brand new commercial opportunities. Our 2021 sales increased to SEK 15.4 million, which is nearly double what we sold for the year before. This success is driven by very strong organic growth with new and returning leading global customers. Our acquisition of a profitable and growing company also expanded revenue in November and December.

SenzaGen has established a presence in several markets: cosmetics, chemicals, pharmaceuticals and medical devices. Demand for non-animal solutions is on the rise and the drivers are strong both from regulators and from public opinion seeing animal welfare and sustainability as important causes. The increasingly advanced technology, which leads to new methods that provide better and more human-relevant results, is also of great significance. Technological developments allow animal tests to be replaced on a broader scale, in which our GARD® technology stands out for being on the cutting edge.

To harness the great potential for non-animal toxicology and for transforming the entire global testing industry, we have implemented a strategy that, in addition to organic growth, includes the acquisition of profitable and growing companies. SenzaGen aims to take the lead in non-animal testing by acquiring specialized companies with cutting-edge expertise. Combining organic growth with acquisitions relatively early in the Company's development like this lays the foundation for us to become a leader in more key *in vitro* toxicology markets.

The acquisition of VitroScreen was completed in November and the integration process is proceeding well. With VitroScreen as a Group partner, we not only created increased revenue, a stronger offering but also a larger toolbox and a broader customer base. We also created new product development opportunities allowing our researchers and engineers to benefit from each other's technology platforms and innovations. Additionally, we gained a commercially stronger position among market participants and broadened our network of industry, research, regulatory and NGO contacts. VitroScreen CEO Marisa Meloni plays a key role as she further strengthens SenzaGen's business growth with her knowledge and large network in the world of *in vitro* toxicology.

Our customer base is growing and SenzaGen exhibited a very strong organic sales trend during the year. Two major new customers tested substances with GARD® – a pharmaceuticals company and a cosmetics company, both among the largest in their industry; the latter recently placed a follow-on order for SEK 1 million. More new customers were acquired, and we saw a steady stream of returning customers, especially from the medical devices and chemicals industries. Our researchers have also engaged in scientific collaboration with global world leaders including Corteva, Essity and Sonova, which increased brand recognition and further improved development opportunities for the Company.

We engage in ongoing dialogue with the authorities in an aim to get our groundbreaking GARD® technology approved by the OECD. In mid 2021, a major regulatory milestone was achieved when the EURL ECVAM scientific advisory committee (ESAC) recommended that the OECD add GARD®skin to its list of internationally approved test methods. The process has been lengthy because it is the first test the committee has deliberated on that is based on genomics, machine learning and cloud data storage. However, interest has been high, because new technology is the future of vitro toxicology. Once OECD approval is in place, results from GARD®skin will be usable for product filings in all OECD member countries – which is expected to significantly increase demand.

In light of the Company's positive performance in 2021, SenzaGen is poised for a strong commercial future: sales are increasing, our customer base is growing and the VitroScreen acquisition has improved our offering and our market presence.

Sales activities and growth will remain our top priority in 2022 while we continue to work on our acquisition agenda. In parallel, at the start of 2022, we already launched a joint test and service offering with VitroScreen targeting the medical devices industry. This joint offering creates new prospects for faster and more cost-effective expansion in the crucial medical devices market.

We are in an exciting time in an expanding industry in which interest in non-animal solutions is growing as technology progresses and regulatory changes come into effect. I am proud to lead the Company through this eventful phase. However, our successes would not have been possible without the hard work of our employees and the support of our shareholders. I would like to express my sincere gratitude to all of you.

Lund in March 2022

Peter Nählstedt, President and CEO SenzaGen

Growth strategy

VISION

Replace animal testing with best-in-class *in vitro* technology
Establish new industry standards
Contribute to safer products in society

GROWTH STRATEGY

Organic growth | **Acquisition-driven growth**

STRATEGIC INITIATIVES

- Drive direct and distributor sales
- Obtain regulatory status for GARD®
- Broaden complementary test services
- Develop novel non-animal solutions
- Acquire complementary profitable growth companies
- Realize synergies between Group companies

SenzaGen's strategy has been developed to expand the Company's operations and make it a leading supplier of high-performance *in vitro* tests. The updated strategy combines organic growth with acquisition activities and can be summarized as follows:

- Continued commercialization and regulatory acceptance of the GARD® platform in Europe, North America and parts of Asia.
- Expansion of the Company's test portfolio by adding high-tech *in vitro* tests to support customers in cosmetics, chemicals, pharmaceuticals and medical devices with a broader range of tests.
- Active acquisition agenda with a focus on profitable and growing companies with complementary offerings.

FOCUS

Product safety and quality rules and requirements differ between different geographic markets and industry segments. As a result, SenzaGen has chosen to primarily focus on the markets and segments where regulations and industry forces are driving the need for more accurate and non-animal tests:

- Cosmetics
- Chemicals
- Pharmaceuticals and nutrition
- Medical devices

By identifying strategically important customers in the industries where regulatory changes are underway or have already been adopted, the Company can meet the increasing need for non-animal tests.

ORGANIC GROWTH

The Company will drive organic growth by working closely with new and existing customers and leveraging a network of distributors and contract research organizations (CROs). Tests are performed at one of SenzaGen's modern, high-tech laboratories:

- SenzaGen AB in Lund is one of the only Nordic GLP-certified CROs for cell-based toxicology testing and serves as the Company's hub for customer studies, research and product development of the GARD® platform.

- VitroScreen s.r.l in Milan is a GLP-certified CRO with more than 20 years of *in vitro* testing experience and serves as the Company's center for customer studies using 3D models, preclinical testing and development of the ORA® platform.

Drive direct and distributor sales

The largest share of SenzaGen's revenue currently comes from direct sales of tests performed in the Company's own laboratories. On behalf of customers, the laboratories perform tests to evaluate the toxicological effects or preclinical efficacy of various substances. This work leads to insights on customer testing needs and provides more knowledge about the GARD® and ORA® platforms' capacity and how to develop new sustainable tests.

To boost GARD® sales, the Company also works with a global network of licensees and distributors comprising CROs specializing in *in vitro* toxicology testing and who already have a network of customers in various industries.

SenzaGen has around a dozen distributors with excellent local market knowledge that play an important role in building relationships and driving sales in the industries in which they specialize. The distributors market GARD® in their test portfolio and the tests are performed in SenzaGen's lab in Lund. SenzaGen also has license agreements with CROs that market, sell and perform GARD® under license: In Germany, Eurofins BioPharma Product Testing Munich, and in the US, Burleson Research Technologies and MB Research.

Obtain regulatory status for GARD®

SenzaGen tracks relevant regulations and standards to ensure that it can make the most of opportunities and market potential. The OECD, ISO and FDA are among the regulators and standard setters for existing GARD® tests. Regulatory approval broadens the area of usage and enables customers to use test results from GARD® not only in the product development phase but also for product filings.

Broaden complementary test services

Demand for CRO services for non-animal toxicology testing is on the rise in the Company's prioritized markets, and SenzaGen aims to continuously expand its range of tests to meet customer preferences and needs. The part of the offering currently being broadened is the regulatory test portfolio for toxicology.

Develop novel non-animal solutions.

The expansion of the Company's test offering also includes the future development of new innovative tests and solutions for more endpoints. SenzaGen has vast expertise in 3D human tissue models, genomics and machine learning, which can be combined to create new solutions in the future.

ACQUISITION-DRIVEN GROWTH

Acquire complementary profitable growth companies

Complementary mergers and acquisitions are a key part of SenzaGen's new growth strategy. The Company is looking for acquisition opportunities with a focus on innovative companies that are profitable and growing with complementary offerings, in terms of both *in vitro* tests and customer portfolios with access to new segments and geographies.

Realize synergies between Group companies

SenzaGen has an effective integration plan in place to identify and optimize synergy effects between Group companies. These synergies are commercial, administrative and operational in nature:

- Cross selling with joint sales force
- Upselling via access to each other's customer bases
- Allocation of tests to specific labs within the Group
- More cost-effective procurement and other administrative and operating activities

Trends and **drivers**

SenzaGen operates in a global market with high growth potential. Chemicals, pharmaceuticals, medical device and cosmetics companies are all looking for alternative test methods that are more accurate, ethical and cost-effective in the long term. There is a trend toward replacing animal testing with non-animal test methods.

TRENDS

Increased focus on alternative tests

The global need for alternative test methods is growing as animal tests are banned and regulations increasingly advocate for alternative test methods. More and more countries are following the EU and imposing bans on cosmetic tests on animals, including Norway, individual US states and Brazil.[1] Important changes are also underway in medical device regulations, which are expected to result in an increased number of tests using non-animal methods, thereby creating new market opportunities for the Company.[2,3]

Additionally, tens of thousands of new chemicals have been introduced into everyday environments over the past decades, which makes high product safety of the utmost importance for companies selling consumer products. By testing the health impact of chemicals before they are used in products such as cosmetics, colors, cleaning products and materials, the manufacturer can replace them with safer substances, thus both reducing the risk of and avoiding clinical symptoms. This trend creates additional opportunities for SenzaGen.

About *in vitro* testing

In vitro testing is increasingly used because the testing process is faster and the results are more accurate than *in vivo* testing on animals. In addition, *in vitro* testing is less expensive and enables a significant decrease in the number of laboratory animals.

MARKET DRIVERS

Industry data from Kalorama show that the market drivers of industry's preferences for *in vitro* testing over *in vivo* testing are linked to regulatory, scientific, ethical and financial considerations.[4] With these drivers as a basis, the Company estimates that industry needs for new technology and alternative testing methods are high and steadily increasing.

Cost-effectiveness

In vitro testing can be performed faster and is less resource-intensive, thus making it more cost-effective most of the time. The ability to perform highly accurate tests on chemical substances early in the research and development process allows companies to rule out substances and product candidates that will not reach the market because of their toxicology profiles. This represents great potential for cost savings in industries such as pharmaceuticals. Statistics show that the development time for a drug can last 10 to 15 years, and that usually only one in 10,000 tested chemical substances make it into the approved drug.[5,6] Given the frequently long development times and major development expenses, delays due to toxicology profile testing in drug candidates could result in USD 500,000 in lost revenue per day.[7]

Need for better test results

Animal tests have limited accuracy. Therefore, they provide an uncertain view of what will happen when chemicals come in contact with the human body. The cosmetics, chemicals, pharmaceuticals and medical devices industries need access to more accurate test methods to ensure the products launched on the market are not harmful and that their efficacy is acceptable.[8]

The ability to perform highly accurate tests on chemical substances early in the research and development process allows companies to avoid unnecessary development expenses for harmful or potentially harmful substances and/or products. Having to recall harmful products from the market can be both expensive and damage the company's brand.

Bans on animal testing

In 2013, all forms of animal testing in the development of cosmetics and hygiene products were banned in the EU.[9] This means that no new products that require testing can be developed without the use of an alternative test method. Several other countries have followed the EU and banned animal testing.

Demands to abandon animal testing are also on the rise in the chemicals, pharmaceuticals and medical devices industries. In the chemicals industry, the REACH regulation increased requirements for the classification of chemicals based on their allergenicity with a preference for *in vitro* alternatives. The recently updated ISO standard 10993-10 recommends that alternative methods to animal testing be used, and the EU's implementation of the Medical Device Regulation (MDR), both of which involve medical devices, are also expected to increase the number of non-animal tests in this sector.

Increased social engagement

Consumers are putting pressure on industries by demanding products developed and produced with a minimal impact on animals and the environment. As a result, companies and industries are implementing Corporate Social Responsibility (CSR) policies, and the Three Rs are a fixture of both Swedish and European legislation involving animal testing. The Three Rs aim to get researchers to use as few animals as possible and also work to alleviate and improve the situation of animals in animal testing. The Three Rs are replace, reduce and refine.[10]

For sources, see page 65.

Size and **potential**

The *in vitro* toxicology testing market is a relatively new market that started to expand in the 2000s as alternatives to animal test methods were developed and began to be used.

Historically, animal testing has played a significant role in obtaining knowledge on and developing treatments for diseases, but there are differences between humans and animals. New, non-animal models (*in vitro* methods) have major advantages and are better suited for us humans.

IN VITRO TOXICOLOGY MARKET

According to market data from Kalorama, the global market for *in vitro* toxicology testing is growing annually by 6.8% and is expected to be worth approximately SEK 80 billion by 2023. This growing market comprises ten subsegments categorized based on the toxicological endpoints they address.

Europe is the largest region followed by North America. Several countries in the Asia-Pacific region are growing rapidly as they advance with alternative test methods and mandatory bans on animal testing. The most important industries are cosmetics, chemicals, pharmaceuticals and medical devices.[11]

CURRENT TARGET MARKET

An expanded test offering and the VitroScreen acquisition have given SenzaGen access to several new toxicology subsegments. Overall, the market for these segments is expected to be worth about SEK 30 billion by 2023, representing around one-third of the total *in vitro* toxicology market.

Skin sensitization, irritation and corrosion

Skin sensitization (skin allergies), combined with irritation and corrosion, is one of the ten subsegments of *in vitro* toxicology testing and accounts for approximately 6% of the total market. The segment is growing the fastest of all segments, by 9.5% annually, and is expected to be valued at approximately SEK 5 billion by 2023.

Respiratory sensitization

Testing of respiratory sensitization (respiratory allergies) is not yet legally required in any industry, but ethical imperatives and industry forces are pushing for safer products. The Company's analysis of clinical trials shows that there are two and a half times more pharmaceuticals developed in inhaled form than products applied to the skin.[12] The Company estimates there may be just as many respiratory allergy tests as skin sensitization tests in the long term.

Cytotoxicity

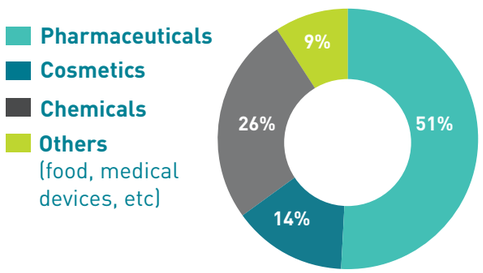
Cytotoxicity (toxicity to cells) testing is a part of the biological evaluation that all medical devices must undergo before being brought to market. At the start of 2022, SenzaGen broadened its offering for medical device customers in this segment, which created additional opportunities for the Company. The segment's total value is estimated to reach approximately SEK 12 billion by 2023.

Foothold in new subsegments via acquisition

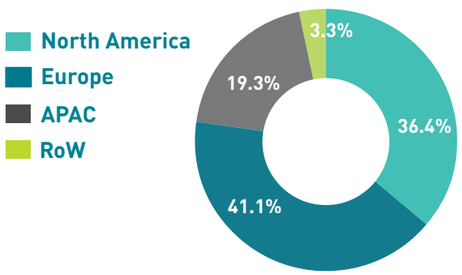
The VitroScreen acquisition adds new subsegments of *in vitro* toxicology testing for SenzaGen and is expected to significantly expand the Company's potential market. The acquisition gives the Company access to parts of the following segments: phototoxicity (toxicity on exposure to sunlight), ocular toxicity (eye toxicity), skin toxicity and other toxicological endpoints/tests, whose combined value is estimated to reach approximately SEK 18 billion by 2023. In addition, a new area was established, preclinical efficacy testing, which provides the opportunity to address customers in parts of a new market segment in which the Company assesses demand is growing and significant from the pharmaceuticals and cosmetics industries.

***In vitro* toxicology market**[11]

Industry segment distribution



Geographic distribution



Exchange rate: USD 1 = SEK 9.80

REGULATORY REQUIREMENTS

SenzaGen tracks relevant regulations and standards to ensure that it can make the most of opportunities and market potential. The OECD, ISO and FDA are among the regulators and standard setters for existing GARD® tests.

An OECD validation process is underway for the GARD®skin and GARD®potency tests. In July 2021, EURL ECVAM's Scientific Advisory Committee (ESAC) issued a positive opinion on GARD®skin and recommended that the OECD add the test to its list of internationally approved skin sensitization test methods, a major and important step toward regulatory acceptance. GARD®potency was recognized as a functional test for the product development phase but more work is required before the test can be recommended for regulatory use.

In the medical devices segment, GARD®skin Medical Device was included in the annex for the update of the new ISO standard, which was published in fall 2021. The Company also filed a Medical Device Development Tools (MDDT) submission with the American FDA. The aim of the submission is for the FDA to qualify the test for the development and evaluation of medical devices.

Testing during the product development phase

At present, SenzaGen sells its GARD® tests primarily to companies that test chemical substances in their product development operations. Chemical testing during the product development phase is not subject to the same regulations as the end products that will be put on the market.

Testing for regulatory filing

Tests validated by the OECD under the applicable regulatory guidelines reach a broader market and achieve regulatory acceptance because they are included in the OECD's official guidelines. For regulatory filing, most regulators also allow the use of test information from non-validated sources that provide sufficient evidence. This means that the results from the GARD® tests can currently be used for filing as a weight-of-evidence submission.

After receiving OECD approval, the application area for SenzaGen's tests will be broadened to include product testing in preparation for regulatory filing in industries such as the cosmetics and chemicals industries in the EU, US and parts of Asia.

The global market for *in vitro* toxicology testing (2018-2023) ($, millions)[11]

Toxicology tests and endpoints	2018	2023	CAGR,%
ADME-Tox	1,700	2,300	6.2
Skin irritation, corrosion, and sensitization	350	550	9.5
Genotoxicity	800	1,100	6.6
Cytotoxicity	950	1,390	7.9
Ocular toxicity	300	400	5.9
Organ toxicity	600	790	5.7
Phototoxicity	220	290	5.7
Dermal toxicity	200	260	5.4
Carcinogenicity	430	650	8.6
Neurotoxicity	230	300	5.5
Other toxicity endpoints & tests	600	850	7.2
Total	**6,380**	**8,880**	**6,8**

For sources, see page 65.

SENZAGEN'S OFFERING

Tests, advice and innovation services

SenzaGen is an innovative company that has developed a cell-based technology platform that replaces animal testing in assessing whether chemicals can cause allergic reactions on the skin or in the respiratory tract. During the year, the Company's regulatory toxicology test range was broadened and the Vitro-Screen acquisition further expanded its offering. Also, a new area, preclinical efficacy testing, was established along with advisory and innovation services based on a patented organoid platform.

INNOVATIVE TEST PLATFORMS

The GARD® platform for skin and respiratory allergies

Based on the GARD® technology platform, SenzaGen has developed tests that determine whether a substance can cause allergies and provides information on whether the allergenicity of the substance is strong or weak. The platform combines genomic data from human cells with machine learning, making the method both more effective and more accurate than traditional animal-based methods. In addition, the method is less expensive and contributes to reducing the number of laboratory animals. The GARD® platform is broadly applicable in all relevant industries and for highly difficult-to-test substances as well. The platform also has potential for use in several more testing and application domains.

The GARD® tests are used in product development and can currently be used for product filings as a weight-of-evidence submission.

GARD®skin

GARD®skin is used to assess whether a chemical substance can cause skin allergies. With proven accuracy up to 94% depending on the application area, the test helps developers and producers ensure that the products they bring to market are free of allergies.[13] The test supports pure chemicals but also substances traditionally considered difficult to assess, such as complex mixtures. The target group is companies in the cosmetics, chemicals and pharmaceuticals industries. The EURL ECVAM scientific committee (ESAC) has issued a clear recommendation that the test become an OECD test guideline for regulatory use.

GARD®skin Medical Device

GARD®skin Medical Device is the first skin allergy test on the market developed specifically for medical devices. GARD®skin Medical Device is an expanded application domain of GARD®skin and is designed for medical device companies that perform ISO risk assessments of their materials. GARD®skin Medical Device is included as an *in vitro* method in the most recent ISO standard 10993-10.

GARD®skin Dose-Response

GARD®skin Dose-Response provides information on the dose at which a substance causes skin allergy. The test enables companies in industries including cosmetics, pharmaceuticals and chemicals to identify the highest possible concentration of a chemical that they can include in their products ("the Dose of Departure"). This serves as crucial information for prioritization and decision-making in research and development. The test is a new application area for GARD®skin, providing quantitative information, and is one of the first of its kind on the market. In 2021, the Company saw substantial demand for the test.

GARD®potency

GARD®potency is the first non-animal test method that provides information on whether the skin allergenicity of a substance is strong or weak under the Classification, Labelling and Packaging (CLP) EU Regulation. A substance with strong allergenicity is classified as category 1A and a substance with weak allergenicity goes under category 1B. The test can be used in combination with GARD®skin and provides qualitative information about the substances assessed as allergenic.

CUSTOMER STORY: Essity Hygiene and Health AB

Skin sensitization

GARD qualified for skin sensitization testing at Essity Hygiene and Health AB

"Essity has recently qualified the GARDskin Medical Device assay for use with our absorbent hygiene products as a potential way of doing sensitization investigations, should need arise. The qualification used baby diapers and feminine pads as model products. The result indicated that the method works for our products and also – happily – that they are not to be classified as sensitizers."

Peter Molin, Product Safety Specialist, Essity Hygiene and Health AB

More reading

Poster investigating a face mask and nitrile gloves, presented at Eurotox 2021: *Assessment of the skin sensitizing potential of pandemic-associated medical devices using the GARD®skin Medical Device assay*

GARD®air

GARD®air is used to assess whether chemical substances in product candidates can cause respiratory allergies. The test is the first on the market, and is recommended for use during the research and development process. Evaluating whether a chemical could impact the respiratory system is also important for manufacturing in industries such as cosmetics, chemicals and pharmaceuticals and for specific occupational groups, such as painters and hairdressers. GARD®air's development has been supported by the EU's SME program Horizon 2020.

The ORA® platform for organ toxicity and efficacy

Organoids, which are mini models of human organs, are used in both basic research and drug development to test the efficacy of substances, but they are also used for safety testing of chemicals and other substances. VitroScreen's proprietary organoid model ORA® helps produce results that are better and safer for humans in terms of drug absorption in the body, making the method both more effective and more reliable than traditional animal tests.

VitroScreen commands expertise spanning the entire organoid platform testing chain with development, production, testing and consultation. The ORA® platform can be tailored to a specific test method, cell or organ type and represents a significant and growing share of the Company's sales.

Microbiome platform

The rapidly growing microbiome domain requires specific tools to test the new products now being developed in the nutrition and pharmaceuticals industries. VitroScreen offers colonized 3D tissue models, models made of human tissue that have been colonized by microorganisms, to study host-microbe interaction. These unique models give researchers the capability to study how both hosts and microorganisms react when they are exposed to chemicals or changed external conditions. Additionally, the tests are offered without 3D models to measure prebiotic and antibacterial efficacy and biofilm formation.

GLP REGULATORY TOXICOLOGY TESTING

Methods approved as OECD guidelines

SenzaGen and VitroScreen offer several regulatory tests, meaning tests that are approved as OECD guidelines, to evaluate the toxicological endpoints and safety of substances, such as irritation tests for the skin, eyes and other tissues. Testing and assessing the potential risks and toxicity of chemicals, cosmetic drug candidates and medical devices is required for regulatory product filings. Both of the companies' CROs in Lund and Milan design and perform both GLP and non-GLP studies.

Regulatory toxicology test portfolio

Endpoint	Test
Skin sensitization, GARD®*	OECD TGP 4.106*
Skin sensitization, others	OECD 442C/D/E
Skin irritation	OECD TG 439, ISO 10993-23
Skin corrosion	OECD TG 431
Phototoxicity	OECD TG 432
Eye irritation	OECD TG 492
Irritation for various tissues	ISO 10993-23
Cytotoxicity	ISO 10993-5
Skin toxicity/absorption	OECD TG 428

PRE-CLINICAL EFFICACY TESTING

Penetration, absorption and distribution

VitroScreen provides tailored studies based on human 3D tissue models to see how substances penetrate tissues and how they are absorbed and distributed in the body. The results can be used to classify substance-based medical devices and are also highly important for companies in the pharmaceuticals industry, where it is crucial to understand whether a product candidate is capable of reaching the right place in the body in the right concentration.

Mechanism of action

VitroScreen offers a broad range of tests to identify or rule out a pharmacological, immunological or metabolic mechanism of action in drugs and medical devices. The mechanism of action can be identified using data from VitroScreen's 3D tissue models, which are available for several indication areas: the skin, legs, eyes, respiratory tracts, gynecology, urology, the abdomen and the liver.

INNOVATION AND ADVISORY SERVICES

Tailored solutions

SenzaGen and VitroScreen leverage their experience and knowledge in the fields of *in vitro* toxicology and preclinical testing to offer tailored solutions based on the companies' patented technology platforms, GARD® and ORA®, and based on VitroScreen's experience in 3D models, microbiota and histomorphology. The innovation units solve customer-specific challenges in various domains of the pharmaceuticals, cosmetics, nutrition and chemicals industries.

Expert support

The companies also offer *in vitro* toxicology expert support and provide guidance on how necessary and scientifically significant tasks should be combined for each customer project, such as for biological evaluation of medical devices.

* Results from the GARD® tests can currently be used for product filings as a weight-of-evidence submission.

VITROSCREEN ACQUISITION

Creates **growth opportunities**

The acquisition of VitroScreen, which was completed on 2 November 2021, enables SenzaGen to offer a unique combination of non-animal services comprising regulatory toxicology and preclinical efficacy testing, toxicology advisory services and innovation services for product development in industries such as pharmaceuticals and cosmetics.

The acquisition gives SenzaGen a significantly **broader offering** and a much larger market, enables sales of VitroScreen's products and services to expand to **more geographic markets** and open up future opportunities to apply the two patented technology platforms, GARD® and ORA®, in **more application areas**.

About VitroScreen
Founded in 2001 in Milan, VitroScreen is a reputed CRO and a leading laboratory for *in vitro* research. The company offers a broad range of regulatory tests for toxicology and preclinical testing, advisory services, and human 3D tissues and organoid models as a foundation for development and innovation. VitroScreen is a growing and profitable company. Its 2020 sales were about SEK 16 million with a 70% gross margin and an EBITDA margin of approximately 6%. The consideration for the acquisition was €2.6m, €0.6m of which was paid in SenzaGen shares and the rest in cash. There is an option for additional consideration up to €1.4m depending on whether certain financial targets are met during the period until 2024.

Growth via broader customer base and cross selling
Together, SenzaGen and VitroScreen have a customer base spanning some of the world's most successful brands in the cosmetics, chemicals, medical devices, pharmaceuticals and food industries. VitroScreen's customers are mostly in Central and Southern Europe while SenzaGen's customers are primarily in Northern Europe, Central Europe and the US. Given that the two companies have a non-overlapping customer base, there are excellent opportunities for cross selling and increased revenue.

Growth via expanded *in vitro* offering
The acquisition adds new subsegments of regulatory *in vitro* toxicology testing for SenzaGen and is expected to expand the Company's available market to approximately SEK 30 billion in total. The acquisition also adds new services in preclinical efficacy testing, toxicology advice and tailored customer solutions, which gives SenzaGen access to increased revenue.

Growth via innovation – expansion to new application areas and market segments
The VitroScreen acquisition adds significant experience and knowledge to SenzaGen regarding *in vitro* toxicology, preclinical testing and innovation services based on human 3D and organoid models, which opens up new future possibilities for innovative projects and new applications of both companies' patented technology platforms: GARD® and ORA®. VitroScreen is also active in market segments that are new to SenzaGen, such as nutrition.

Efficiency gains via procurement and expertise
Coordinating procurement volumes with the largest joint suppliers is expected to make savings possible for raw materials. Additionally, the companies are given the opportunity to collaborate and share best practices with each other, which will lead to improved efficiency in each of their operations.

Since opening VitroScreen in 2001 Dr. Marisa Meloni revolutionized the field of alternatives to animal testing. The success of the business is rooted in the conviction that *in vitro*-reconstructed human tissues and spheroids provide highly relevant biological models that mimic the complexity of human physiology and the dynamic nature of the *in vivo* systems.

"Twenty years ago, VitroScreen opened the door to novel *in vitro*-based testing models," says Dr. Marisa Meloni. "Over the years, we have demonstrated that by combining advanced biological systems as 3D reconstructed tissues with a quality-oriented approach it is possible to apply *in vitro* models not only to regulatory toxicology (often referred to as Alternatives to animal testing) but also to preclinical research and mechanisms of action identification. The proposed new approach to preclinical testing was based on robust experimental designs that focused on biological relevance, reproducibility and predictivity versus humans. Consequently, it was applicable to almost all industries: cosmetics, pharmaceuticals, medical devices, nutrition and chemicals."

A cornerstone of VitroScreen's success has been its belief and its investment in biological models issued from tissue reconstruction by airlift, an emerging technology when VitroScreen started its activities in 2001.

"Devising new experimental models has been a unique experience. We have always focused on creating unique, fit-for-purpose models that are based on human relevance, mirroring human physiology both in health and disease," says Marisa Meloni. "Over the years, the team at VitroScreen has established a significant amount of novel experimental models first with 3-dimensional human tissue samples and more recently with spheroids and organoids as Micro Physiological Systems (MPS). It has been an adventure for all of us."

MPS developed within the VitroScreen ORA® platform are systems that mimic closely the physiological landscape of various organs, tissues and body barriers—following the concept of providing 'mechanism-based experimental models'.

An innovator in its field, VitroScreen has developed a variety of MPSs that target specific therapeutic areas. The essence of the company's unique approach is based on building life-like 'bundles' where organo-specific cells produce their specific microenvironment, extracellular matrix, thus mirroring physiological architecture, tissue polarization and surface properties.

"At VitroScreen, we have always been guided by Galileo Galilei's motto: "*Quid mensura mensuratur ut quod non mensuratur*" that is, to measure what is measurable and to make measurable what is not."

Interview with Dr Marisa Meloni, CEO and founder of VitroScreen

An **innovative** company in its field

Tell us about your passion for your industry and how it all began
Marisa Meloni grew up in Sardinia in the heart of the Mediterranean Sea. She learned the art and mindset behind pharmaceutics from her father and grandfather, who ran a family business in this area. After her PharmaD degree from the University of Sassari, she got a grant to explore uncharted areas of botanicals to apply their biological properties in life science from CNR (Consiglio Nazionale Ricerche), the National Research Council of Italy.

"One of my passions is to discover and understand the mechanism of action behind biologically active molecules," she explains.

After spending several years in Paris, her passion led her to apply for a PhD in Biophysics at René Descartes University. Here she was introduced to the emerging new standards in the life sciences that she eventually shaped into her VitroScreen vision. However, first she was to spend over a decade learning how the pharmaceuticals and cosmetics industries tick.

In 1999, Dr Meloni was invited to give a lecture at the prestigious European Cosmetics Association, formerly named 'Colipa' (an acronym initially standing for "Comité de Liaison de la Parfumerie") and now called 'Cosmetics Europe - The Personal Care Association'. Colipa was the flagship of the cosmetics industry's commitment to Alternatives and the theme of the meeting was 'Alternatives to animal testing.'

At the time, Dr Meloni was employed as Research and Development Innovation Manager at a cosmetics company. "It was the time of the EU's VI Amendment to the Cosmetics Directive and the industry was concerned about the lack of alternative models for animal testing," Marisa Meloni recalls. "Various speakers showed that, at that time, an increase in *in vivo* testing (either on animals or on humans) was being performed by contract research organizations to fulfil cosmetics dossier requirements. The industry appeared to have few alternative solutions." Marisa Meloni saw two points of concern: first, the continued extensive use of animals as the first step for hazard identification and, second, the potential use of humans for risk assessment. "I had a clear vision of my priorities as a scientist. That was to create and foster knowledge of *in vitro* science and to apply *in vitro* approaches at all industry levels by introducing human relevant models and new upcoming technologies," Marisa Meloni says.

"I was convinced that the life sciences industry would adopt more sustainable, ethical and scientifically robust testing strategies in the near future."

Marisa Meloni focused her efforts on investing in and disseminating the 3Rs principles and in particular on developing the applications of 3D tissue models and advanced technologies across the life science industries. "It was 2001 and there were just a handful of validated alternatives at the OECD. Virtually no one would trust me!" The most frequent question she faced was "Are the test/approaches you propose validated?" And since most were not, she was surrounded by broad scepticism. She found it difficult to convince people that adopting non-validated alternatives would establish the required knowledge-based evidence to accept *in vitro* data in the future."

VitroScreen was established in 2001, instantly changing the playing field regarding alternatives to animal testing. "I was driven by the idea that it was the right thing to do and I put all my passion into our venture," Marisa Meloni says. "Above all, I did and am still doing what I love to do. I remain committed to enlightening the scientific community and the broader life science industries that it is the right thing to do."

"Life science industries trust our *in vitro* approach not only because regulatory authorities around the world are pressuring them to develop and apply alternative approaches, but also because they are human-relevant, predictive, reproducible and robust. In particular, I think that life science industries are interested in our models and in our activities because VitroScreen, as a research outsourcing laboratory, has demonstrated it proposes the best *in vitro* strategy adapted to solve "real-life" R&D problems, simultaneously providing a more ethical solution.

Last but not least, we are open to partnership and eager to invest along with our partners in ever more novel and more robust solutions optimized to deliver relevant pre-clinical models."

What do you want to learn from your colleagues in Lund, and what skills and expertise can you convey to them?
It will be a new and really exciting adventure! The application of GARD® technology based on machine learning as well as a deeper investigation of genomic and proteomic approaches applicable to mechanisms different from sensitization is at the core of SenzaGen's expertise; there is a world of opportunities that can be explored by combining our expertise in preclinical modelling with state-of-the-art technologies. And we are just at the beginning of our journey together!

SENZAGEN'S TECHNOLOGY PLATFORMS

GARD®

SenzaGen's GARD® (Genomic Allergen Rapid Detection) platform comprises a series of tests that are all designed according to the same principle and are based on the analysis of a human cell's total response when exposed to different substances. At present, SenzaGen's products are focused on detecting and identifying the allergenicity of chemical substances – a process also referred to as sensitization.

To develop a method with high accuracy, SenzaGen uses dendritic cells – a cell type that plays a central role in the human immune defense against foreign substances. The Company examines the cell's total response, the entire gene expression, when it is exposed to allergenic substances and compares this with the response to substances that are not allergenic. The genes whose expression changes in different ways depending on whether the cell is exposed to an allergenic substance or a non-allergenic substance create a gene signature that can be used to identify the allergenicity of other substances. To further increase accuracy and sensitivity, the Company uses machine-learning methods specializing in pattern recognition. Modern data processing technologies and artificial intelligence are leveraged so all the information in a human's genetic material, genomics, can be used to provide an accurate answer as to whether a substance causes allergies.

Sensitization

The first step in the development of an allergy is sensitization to the substance. Sensitization occurs when substances the body considers foreign come in contact with our immune system for the first time. Allergies are caused by proteins or substances such as chemicals that are small enough to be absorbed via the skin, respiratory tract or other means. If these are considered foreign by the dendritic cells and also give rise to immunological "danger signals" and co-stimulation, sensitization occurs, which can lead to an allergy such as contact eczema or allergic asthma if the individual is exposed to the substance again. GARD® is designed to assess a substance's capacity to cause sensitization.

Genomics

In total, there are approximately 25,000 genes in our genetic material that each have different tasks and express or turn off as needed. Genomic tests have the capability to examine all of these genes and how they are regulated in a cell, tissue or organ in response to various circumstances. Examining all genes gives us a detailed view of, for instance, what happens in a dendritic cell when it is exposed to an allergenic substance. Understanding and analyzing all the information usually requires modern data processing. GARD® is based on a gene structure developed using genomics, statistical analysis and machine learning.

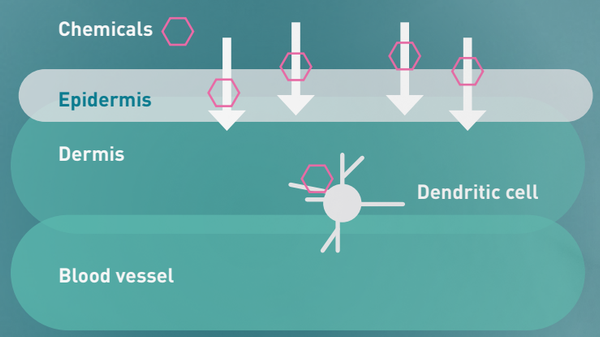
Machine learning

Modern machine learning allows computers to recognize patterns in large quantities of data. The term machine learning refers to computers' ability to learn from data without having to be programmed for the specific task. The technology is used for purposes such as image analysis to identify tumors and, in SenzaGen's case, to recognize gene expression in dendritic cells exposed to allergenic substances. By training the Company's model on the gene signatures developed, SenzaGen has succeeded in generating prediction models that accurately classify a substance as potentially allergenic or non-allergenic.

Dendritic cells

Dendritic cells are a type of white blood cell that specialize in identifying foreign substances. When these cells recognize substances that can be harmful to the body, they activate and regulate the other parts of the immune response to handle the foreign substance. The immune system's main task is to protect the body from attacks by various types of microorganisms, such as bacteria and viruses, but sometimes it reacts to other substances, which can lead to an allergic reaction.

When dendritic cells recognize a substance as foreign, they are activated and change their function and appearance. These changes start with the regulation of the gene expression of various genes; this can be measured using various techniques, and this is what serves as the foundation for the GARD® test's capability to differentiate between allergenic chemicals and non-allergenic chemicals.



The structure of dendritic cells enables them to easily absorb foreign substances from their surroundings. The illustration shows how a chemical is absorbed via the skin and transported to the dendritic cell.

SENZAGEN'S TECHNOLOGY PLATFORMS

GARD® – improved accuracy and human relevance

The GARD® assays were developed with a holistic view, utilizing genomics and machine-learning technology to reflect the complex processes underlying an immune response, e.g. skin sensitization. This approach gives GARD® improved accuracy and clinical relevance.

Traditional *in vitro* tests investigate only a few biomarkers and provide limited information to give reliable results. Animal tests provide much more information which, however, is not always human-relevant. By using a genomics-based approach with machine-learning technology, GARD® combines the simplicity of *in vitro* methods and the biological intricacy of *in vivo* models.

This holistic approach contributes to improved accuracy and clinical relevance. For example, the predictive accuracy of animal tests for skin sensitization assessment has been estimated to be 70-75% while GARD®skin achieves predictive accuracy up to 94%, [14,15]

The ORA® platform for organ toxicity and efficacy

Organoids, which are mini culture models of human organs, are used in both basic research and drug development to test the efficacy of substances, but they are also used for safety testing of chemicals and other substances. VitroScreen's proprietary organoid model ORA® helps produce results that are better and safer for humans in terms of drug absorption in the body, making the method both more effective and more reliable than traditional animal tests.

The benefits of the ORA® platform are that the cells grow and are organized spontaneously according to their natural physiology, which means that no artificial frameworks need to be added. Additionally, you only need a relatively low number of cells, and it works for protocols with longer time frames so that the test can be performed at dosages close to *in vivo.*

VitroScreen's proprietary organoid model ORA® helps produce **results that are better and safer for humans** in terms of drug **absorption in the body**, making the method both more effective and more reliable than traditional animal tests.

Sustainability report

The core of SenzaGen's business revolves around innovative tests and services in non-animal toxicology and efficacy testing. These tests enable companies in several industries to provide safe and effective products while creating better production environments for their employees. As a result, SenzaGen's tests contribute to safe, ethical and more sustainable products reaching the market while also reducing the number of animal tests.

2021 progress

In 2021, SenzaGen performed a situation analysis at its headquarters in Lund to obtain a well-founded view of the current situation and identify sustainability issues to systematically work more on. Using a template of questions based on the principles of ISO 26000 (guidance on social responsibility), seven main areas were analyzed: Management control, Human rights, Working conditions, The environment, Good business practices, Customer questions, and Social engagement. In addition, several HR policies were formulated and implemented at headquarters. How we should behave and conduct ourselves externally was specified in a code of conduct that was implemented and applies to the entire Group.

Good business practices

It is important for SenzaGen to always maintain a high level of ethics in business-related situations. This boosts competitiveness and contributes to a strong reputation. In support of this, in 2021, the Company made fundamental values expressed in the UN Global Compact's ten principles clearer in a code of conduct that applies to the Group's employees and board directors. The principles include human rights, working conditions, the environment and anti-corruption, and they provide guidelines for how employees should behave in their day-to-day work and in contact with customers, suppliers, competitors and other external parties. The Group also expects business partners to apply similar standards and principles and their operations and act in accordance with agreed contracts.

In addition to these principles, the Company has separate anti-Corruption directives that both employees and partners are subject to. The Company has a zero-tolerance policy for all forms of corruption, which includes any kind of bribery.

Quality management system

SenzaGen develops tests and analyzes customer samples in compliance with applicable legislation, directives, standards and regulatory requirements. Therefore, quality and quality management are an integral part of the Company's operations.

SenzaGen's quality management system in Lund ensures that its products and services are developed and rendered in compliance with set requirements and support systematic improvements. The quality management system's foundation is the Company's quality manual, which describes what activities to perform and how to shape processes to assure quality.

The Company's quality policy is an extension of the quality manual and is based on the seven quality management principles of ISO standard 9001. The policy reflects SenzaGen's views on quality, and all employees must follow and integrate the policy into their daily work.

GLP-approved lab operations

To meet both the customer's internal quality requirements and the regulatory requirements for study data used in product filings with regulators like the Swedish Medical Products Agency or the FDA, the Group's lab operations in Lund and Milan are GLP-approved. The approval affirms that the Group has ensured that customer studies subject to GLP requirements can be performed with the quality specified by regulators when the study is used as documentation for regulatory purposes. The approval is assured over time via recurring inspections of the Group's operations by relevant entities.

GLP stands for Good Laboratory Practice and is a quality system of requirements and principles to assure the quality of non-clinical safety studies. What constitutes GLP is defined by the OECD for use as a global standard requirement to ensure high-quality and reliable results for product filings and regulatory approval.

Environmental efforts

SenzaGen's day-to-day work both within and outside of its laboratory operations is not energy-intensive and does not have any significant impact on the environment. Also, the Group's operations do not require any permits under Swedish environmental law. At the same time, SenzaGen advocates for and takes measures to improve the environment in every area possible in line with the UN's principles for corporate sustainability. We aim to always use energy, materials and other resources sparingly.

Our main focus is on following the precautionary principle and meeting the Company's strategic initiatives to create efficient workflows, processes and ways of working with the least possible environmental impact. For example, SenzaGen has procedures in place for chemical and waste management in its lab environment and follows the Swedish Environmental Protection Agency's new digital systems for tracking hazardous waste. Procedures are also in place for energy-efficient technical equipment, digital meetings and source-separated recycling.

During the COVID-19 pandemic, travel and physical meetings have been canceled, but SenzaGen plans to create a procedure for minimizing environmental impact and carbon offsetting the business trips and flights the Company needs to take in the future.

In January 2021, the Company's headquarters at Medicon Village in Lund, Sweden were connected to the science park's new technical energy solution, ectogrid. As a result, the buildings in the area now share surplus heat and cooling with one another. The solution disposes of waste heat and is expected to drastically reduce the energy needs of SenzaGen and the other businesses in the area.

Social engagement

SenzaGen gets involved in key social issues in the field of non-animal tests. Initiatives are being pursued in society to reduce, replace and refine animal testing (the Three Rs), with national and international bodies and agencies working to improve animal welfare and to decrease the number of animals used in tests. In the role of experts, several SenzaGen employees participate in a series of working groups to advance broad acceptance of non-animal testing and the Three R Principles:

- Swedish 3Rs Center
- Swedish Fund for Research Without Animal Experiments (Forska utan djurförsök)
- CAAT: Center for Alternatives to Animal Testing in Europe
- ISO 10993 for biological evaluation of medical devices
- OECD Expert Group on IP issues Test Guidance
- ESTIV: European Society for Toxicology In Vitro
- EU-NETVAL: European Union network of Laboratories for the Validation of Alternative Methods.

Working toward measurable goals with Agenda 2030

SenzaGen plans to identify specific and measurable sustainability goals to track sustainability activities and implement these in the development of its entire business. The UN Global Compact and the UN's 17 global sustainable development goals (SDGs) serve as the foundation for these efforts. SenzaGen's business has a clear link to Goal 3: Good Health and Well-Being, especially target 3.9, which aims to reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination.

SenzaGen's employees enjoy skills development and a stable workplace, which affects Goal 4: Quality Education and Goal 8: Decent Work and Economic Growth. By engaging in systematic efforts to minimize the risk of corruption, we contribute to strengthening the rule of law and promoting human rights in Goal 16: Peace, Justice and Strong Institutions.

A stimulating workplace

For SenzaGen, its employees are its most valuable resource. Their well-being, engagement and skills are essential to good performance, high-quality work and the Company's growth. In this area, our focus is on skills development, corporate culture, health and safety.

The right skills and capabilities

Recruiting and retaining qualified and skilled employees is essential to realizing the Company's business strategies. The right experience and engagement along with efficient ways of working are key components of the Company's ongoing growth. SenzaGen frequently plays the role of problem solver for customers, which requires creativity and employees with a high level of business know-how and technical expertise. In addition, processes and work tools must be efficient.

Culture and values

To succeed in its mission, SenzaGen aims to create a culture where every employee is given the opportunity to develop, influence their own work situation and maintain a good work-life balance to avoid stress and illness. To create a strong and sustainable culture, both managers and employees must actively work to establish and maintain the culture envisioned by the organization. An open and transparent corporate culture builds trust, which in turn increases efficiency and opportunities within the organization.

Health, safety and equality

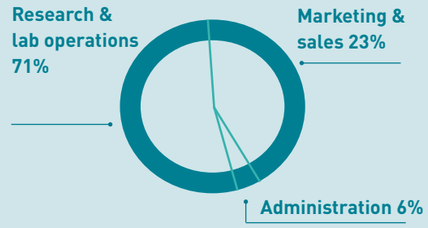
As a responsible employer, the SenzaGen Group does everything it can to promote diversity and good health. SenzaGen seeks to offer a healthy and safe work environment with good working conditions where everyone has equal rights and opportunities and is treated equally in terms of working conditions and terms of employment. All Group employees have employment agreements that comply with national legislation and regulations. In addition, the Company has an established framework with a code of conduct based on the UN human rights that serves as a complement to local legislation and regulations as well as policies for the work environment, for gender equality, and for harassment and discrimination. These HR policies were worked on at headquarters in 2021.

To promote health, SenzaGen offers its employees in Lund a wellness allowance, health checkups and disability insurance benefits. Medicon Village Science Park has a gym and optional group exercise sessions at lunchtime. Questions of well-being, job satisfaction and perceived health situation are taken up during the Company's annual performance reviews. The rate of absence due to illness is low at SenzaGen's headquarters but is continuously analyzed to discover changes.

In 2021, a total of 3 new employees were recruited to SenzaGen in Lund: 1 woman and 2 men. On top of that, 11 employees were added via the VitroScreen acquisition: 9 women and 2 men. The number of employees at the end of the year was 31 (17).

THE GROUP

Area of work



Gender and education

Women 61%

Men 39%

PhD 45%

Values:

Creative, engaged and trustworthy

DIRECTORS' REPORT

The Board of Directors and CEO of SenzaGen AB (publ) (556821-9207), based in Lund, hereby present the annual report and consolidated financial statements for the 2021 financial year.

Business

SenzaGen aims to be a leader in *in vitro* science and testing, driving the transition from animal testing to methods better suited to reflect human biology. The Company provides high-performance, non-animal test methods and innovation and consulting services based on the latest technology. Non-animal methods are more effective, more accurate and less expensive than traditional animal-based methods while also helping to reduce the number of laboratory animals. The Company has a growth strategy centered around continued commercialization of its proprietary GARD® test platform, expansion of its test portfolio and evaluation of acquisition opportunities of profitable and growing companies with complementary offerings. Italian CRO VitroScreen has been a part of the Group since 2021 and provides regulatory tests and advanced innovation services based on 3D models built using human cells.

Group consolidation

SenzaGen is a corporate group consisting of SenzaGen AB, the Parent Company headquartered in Lund, and two wholly-owned subsidiaries, SenzaGen North America Inc (North Carolina, USA) and VitroScreen S.r.l. (Milan, Italy). The Group's employees primarily work at the Parent Company in Lund and the subsidiary in Italy, which are where tests are conducted and the product development and sales functions are performed. The function of the US subsidiary is primarily sales and marketing support for partners.

The number of employees in the Group, converted to full-time equivalent (FTE), was 31 (17) at year-end. 19 (10) of the employees were women and 12 (7) were men. More information is provided under the "Employees" section of the sustainability report on page 31.

Research and development

SenzaGen conducts several research projects to strengthen its product portfolio. The foundation of the Group's product development is the GARD® technology platform, which is broadly applicable in all of the Company's relevant industries and for difficult-to-test substances. The platform also has potential for use in several more testing and application domains. With the help of VitroScreen's proprietary organoid model ORA®, the Group can also provide customers with tailored solutions for a specific test method, cell or organ type. In 2021, the company continued to invest in the GARD® platform's IP protection in several countries in Europe, North America and Asia.

The focus of development operations was on the ongoing OECD validation process where documentation work and supplementary studies were performed to support the application. During the year, the ESAC (EURL-ECVAM's expert group), the part of the European Commission's research and development center that manages alternatives to animal tests, published a report in which GARD®skin is considered ready to become a standard test for skin sensitization in the OECD's test program.

Financial performance

Consolidated net sales for the year totaled SEK 15.4 (8.0) million.

The majority of sales are in EUR and USD to companies outside Sweden, which means that the Company's sales and earnings are impacted by fluctuations in these currencies.

The consolidated operating loss was SEK -31.5 (-27.1) million.

Operating expenses for the year totaled SEK 47.5 (35.3) million including the cost of goods sold. The increased expenses are attributable to investments in R&D, sales and the organizational structure in line with the Company's growth strategy along with SEK 3.8 million in one-off expenses associated with the acquisition and change in CEOs.

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 2.3 (2.4) million, with patents and trademarks accounting for SEK 2.3 (2.1) million of this amount. Capitalized expenditure for in-house development projects totaled SEK 31 (334) thousand.

The Group's cash and cash equivalents at the end of the year totaled SEK 69.2 (89.3) million.

Net cash from operating activities for the year was SEK -21.0 (-29.4) million. Total net cash flow for the year amounted to SEK -20.2 (-31.1) thousand.

During the year, 372,000 stock options were subscribed by employees under the employee incentive programs adopted by the 2021 AGM.

The 2021 Annual General Meeting (AGM) 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 AGM.

To complete the acquisition of VitroScreen, approximately SEK 30 million in capital was raised with a directed share issue.

Significant events during the year

26 Jul. 2021. The EU Reference Laboratory for alternatives to animal testing (EURL ECVAM) informed SenzaGen that ESAC, its scientific committee, had issued a positive opinion on the GARD®skin test method and recommended that the OECD adopt the method as a test guideline for skin sensitization.

18 Aug. 2021. The SenzaGen Board of Directors appointed Peter Nählstedt as the new President and CEO effective 19 August.

29 Sep. 2021. SenzaGen presented an accelerated growth strategy with a focus on organic growth and acquisition activities with profitable and growing companies.

28 Oct. 2021. SenzaGen announced that it had entered into an agreement with the owners of VitroScreen S.r.l., an Italian *in vitro* laboratory with a focus on preclinical testing and innovation, to acquire 100% of the shares, and that SenzaGen planned to issue new shares to finance the acquisition.

29 Oct. 2021. SenzaGen conducted a directed share issue totaling SEK 30 million. By virtue of authorization from the AGM on 5 May 2021, The SenzaGen Board of Directors resolved on a directed share issue of 2,290,694 shares to several qualified Swedish investors, including Fjärde AP-fonden.

2 Nov. 2021. SenzaGen completed the acquisition of VitroScreen S.r.l. for SEK 25.9 million in consideration.

Risks and uncertainties

SenzaGen's business is exposed to several operational risks. These risks mainly comprise uncertainty concerning market growth and product development.

Financing needs and capital

SenzaGen's future plans may result in increased expenses for the Company. A delay in penetrating new markets could result in poorer earnings for the Company. The possibility that SenzaGen may need to raise additional capital cannot be ruled out. Additionally, the Company cannot guarantee that it will be able to raise such additional capital.

Key personnel and employees

SenzaGen's key personnel have great expertise and long-standing experience in the Company's area of activity. Losing one or more key employees could have negative consequences for the Company's business and results of operations.

Competitors

Extensive investment and product development from a competitor could cause risks in the form of poorer sales. Additionally, companies with global operations that currently operate in adjacent areas could decide to expand to SenzaGen's area of activity. Increased competition could have a negative impact on sales and earnings for the Company in the future.

Business cycle and foreign exchange risk

External factors such as changes in inflation, exchange rates and interest rates, supply and demand and expansions and contractions can have an impact on operating expenses, sales prices and share value. SenzaGen's future revenue and share value could be negatively impacted by these factors, which are beyond the Company's control. Part of sales revenue may be received in international currencies. Exchange rates could fluctuate significantly.

Market growth

SenzaGen plans to expand in the coming years by increasing market share in the countries and regions in which it already has sales and by expanding to new countries. Expanding to new countries and regions could result in challenges and risks that are difficult to anticipate. In addition, expansions could be delayed, thus causing losses in revenue. Growth could result in organizational challenges. It could be difficult to find and integrate the right personnel into the organization.

Patents

SenzaGen holds several patents. The Company cannot guarantee that an approved patent will provide effective commercial protection in the future.

Product development

SenzaGen will continue to develop new products and refine existing products in its area of activity. Time and cost aspects of product development could be difficult to estimate accurately in advance. This results in a risk that planned product development activities will cost more in terms of time and money than planned.

Product liability

Considering the nature of SenzaGen's business, it is relevant to take the Company's product liability into account, which arises when the Company develops and commercializes products. The board considers the Company's current insurance coverage to be satisfactory in consideration of the nature and extent of its business. However, there is no guarantee that the Company's insurance coverage will be able to cover any future legal claims in full, which could impact SenzaGen's business and results of operations negatively.

Legislation and regulations

If SenzaGen's business were to be subject to regulatory restrictions or if the Company does not receive required future regulatory authorizations, this could negatively impact SenzaGen commercially and financially.

Outlook

SenzaGen's new growth strategy, which combines organic growth with acquisition activities, is expected to create new opportunities and potential for strong sales performance. The global market for *in vitro* toxicology testing, in which SenzaGen operates, is growing rapidly according to several industry reports. The market drivers of the industry preference for non-animal tests over traditional animal models are correlated with regulatory, scientific, ethical and financial aspects. Chemicals, pharmaceuticals, medical device and cosmetics companies are looking for alternative test methods that are ethically and scientifically superior while also being cost-effective in the long term. In consideration of these market drivers, the Company estimates that industry needs for new technology and alternative test methods are high and rising steadily.

Proposed appropriation of retained earnings

SEK	
The following retained earnings are available for appropriation by the AGM:	
Retained earnings	104,074,405
Share premium reserve	33,348,439
Profit/loss for the year	-31,149,483
The board proposes that the following amount be carried forward	106,273,361

Dividend

The board proposes no dividend for the 2021 financial year.

CONSOLIDATED INCOME STATEMENT

SEK thousand	Note	2021	2020
	1		
Operating income			
Net sales	2	15,422	7,958
Cost of goods sold		-5,969	-2,380
Gross profit/loss		**9,453**	**5,578**
Operating expenses	4,5,6,7,8		
Selling expenses		-21,234	-20,841
Administrative expenses		-15,550	-8,357
Research and development expenditure		-3,874	-2,626
Other operating income		542	249
Other operating expenses		-870	-1,101
Operating profit/loss		**-31,533**	**-27,098**
Profit/loss from financial items			
Interest income and similar items	8	187	76
Interest expenses and similar items	8	-19	-146
Profit/loss after financial items		**-31,365**	**-27,168**
Profit/loss before tax		**-31,365**	**-27,168**
Tax on profit/loss for the year		19	-
PROFIT/LOSS FOR THE YEAR		**-31,346**	**-27,168**
Share of profit/loss attributable to Parent Company shareholders		-31,346	-27,168
Share of profit/loss attributable to minority interests		-	-

CONSOLIDATED BALANCE SHEET

SEK thousand	Note	2021	2020
	1		
ASSETS			
Non-current assets			
Intangible assets			
Goodwill	9, 10	13,109	
Capitalized development expenditure	11	10,631	7,158
Concessions, patents, licenses, trademarks and similar rights	12	25,430	8,209
Total intangible assets		**49,170**	**15,367**
Property, plant and equipment			
Equipment, tools, fixtures and fittings	13	3,230	2,097
Total property, plant and equipment		**3,230**	**2,097**
Financial assets			
Non-current receivables		-	-
Total financial assets		**0**	**0**
Total non-current assets		**52,400**	**17,464**
Current assets			
Inventories		3,201	1,065
Total inventories		**3,201**	**1,065**
Current receivables			
Trade receivables		6,269	1,521
Other receivables		1,348	933
Earned but not invoiced revenue	17	222	
Prepaid expenses and accrued income	17	1,201	1,222
Total current receivables		**9,040**	**3,676**
Cash and bank balances		69,164	89,343
Total current assets		**81,405**	**94,084**
TOTAL ASSETS		**133,805**	**111,548**

CONSOLIDATED BALANCE SHEET

SEK thousand	Note	2020	2020
	1		
EQUITY AND LIABILITIES			
Equity	19		
Share capital		1,203	1,068
Other contributed capital		2,739	5,822
Retained earnings		136,953	128,070
Profit/loss for the year		-31,346	-27,168
Translation differences		694	
Total equity attributable to Parent Company shareholders		**110,243**	**107,792**
Non-current liabilities			
Liabilities to credit institutions		714	-
Total non-current liabilities		**714**	**-**
Current liabilities			
Trade payables		3,135	1,306
Other provisions		6,235	-
Current tax liabilities		440	462
Other liabilities		2,447	702
Invoiced but not earned revenue		1,546	-
Accrued expenses and deferred income	18	9,045	1,286
Total current liabilities		**22,848**	**3,756**
TOTAL EQUITY AND LIABILITIES		**133,805**	**111,548**

CONSOLIDATED CASH FLOW STATEMENT

SEK thousand	Note	2021	2020
	1		
Cash flows from operating activities			
Profit/loss after tax		-31,346	-27,168
Adjustments for non-cash items			
Depreciation and amortization	10,11,12,13	4,268	3,826
Impairment losses	11	-	508
Foreign currency translation, unrealized		6	51
Tax		-39	-
Changes in working capital			
Changes in inventories		45	-361
Changes in current receivables		-1,468	-1,239
Changes in current liabilities		7,554	-4,993
Net cash from operating activities		**-20,980**	**-29,376**
Cash flows from investing activities			
Acquisitions of intangible assets, including capitalized development expenditure	10,11,12	-2,334	-2,425
Acquisitions of property, plant and equipment	13	-331	-21
Acquisitions/disposals of financial assets	9	-23,890	-
Net cash from investing activities		**-26,555**	**-2,446**
Cash flows from financing activities			
New share issue		30,008	-
Transaction expenses attributable to new share issue		-2,306	-
Option premium		8	698
Option repurchase		-352	-
Change in non-current liabilities to credit institutions		-68	
Net cash from financing activities		**27,290**	**698**
NET CASH FLOW FOR THE YEAR		**-20,245**	**-31,124**
Cash and cash equivalents at start of period		89,343	120,467
Translation difference on cash and cash equivalents		66	-
Cash and cash equivalents at end of period		69,164	89,343
Supplementary cash flow statement disclosures			
Interest received during the year		75	76
Interest paid during the year		-16	-1

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

SEK thousand	SHARE CAPITAL	OTHER CONTRIBUTED CAPITAL	ACCUMULATED LOSS	TOTAL EQUITY
Opening balance at 1/1/2017	**108**	**42,555**	**-9,953**	**32,711**
2017 loss			-12,994	-12,994
Bonus issue	433		-433	0
New share issue	232	89,881		90,113
Issue expenses		-9,012		-9,012
Options		257		257
Translation difference			-65	-65
Closing balance at 31/12/2017	**773**	**123,681**	**-23,445**	**101,010**
2018 loss			-16,090	-16,090
New share issue	6	2,334		2,340
Options		111		111
Minority acquisitions			-1,369	-1,369
Translation difference			-66	-66
Closing balance at 31/12/2018	**779**	**126,126**	**-40,970**	**85,936**
2019 loss			-50,237	-50,237
New share issue	281	105,677		105,958
Issue expenses		-10,749		-10,749
Option redemption	8	3,310		3,318
Foreign currency effects			-15	-15
Closing balance at 31/12/2019	**1,068**	**224,364**	**-91,222**	**134,211**
2020 loss			-27,168	-27,168
Options		698		698
Foreign currency effects			51	51
Closing balance at 31/12/2020	**1,068**	**225,062**	**-118,339**	**107,792**
2021 loss			-31,346	-31,346
Non-cash issue	21	6,105		6,126
New share issue	114	28,894		30,008
Options		-344		-344
Issue expenses		-2,307		-2,307
Foreign currency effects			314	314
Closing balance at 31/12/2021	**1,203**	**258,410**	**-149,371**	**110,243**

PARENT COMPANY INCOME STATEMENT

SEK thousand	Note	2021	2020
	1		
Operating income			
Net sales	2,3	12,164	7,958
Cost of goods sold		-4,570	-2,380
Gross profit/loss		**7,594**	**5,578**
Operating expenses	4,5,6,7,8		
Selling expenses		-21,143	-20,941
Administrative expenses		-14,632	-8,357
Research and development expenditure		-3,035	-2,626
Other operating income		454	249
Other operating expenses		-577	-1,101
Operating profit/loss		**-31,339**	**-27,198**
Profit/loss from financial items			
Interest income and similar items	8	190	87
Interest expenses and similar items	8	0	-146
Profit/loss after financial items		**-31,149**	**-27,257**
Tax on profit/loss for the year		-	-
PROFIT/LOSS FOR THE YEAR		**-31,149**	**-27,257**

PARENT COMPANY BALANCE SHEET

SEK thousand	Note	2021	2020
	1		
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development expenditure	11	5,072	7,158
Concessions, patents, licenses, trademarks and similar rights	12	9,689	8,209
Total intangible assets		**14,761**	**15,367**
Property, plant and equipment			
Equipment, tools, fixtures and fittings	13	1,370	2,097
Total property, plant and equipment		**1,370**	**2,097**
Financial assets			
Investments in Group companies	14	31,101	84
Receivables from Group companies		1,085	1,076
Total financial assets		**32,186**	**1,160**
Total non-current assets		**48,317**	**18,624**
Current assets			
Inventories		1,185	1,065
Total inventories		**1,185**	**1,065**
Current receivables			
Trade receivables		3,144	1,532
Other receivables		1,376	931
Earned but not invoiced revenue	17	222	
Prepaid expenses and accrued income	17	1,139	1,215
Total current receivables		**5,881**	**3,678**
Cash and bank balances		67,332	88,961
Total current assets		**74,398**	**93,704**
TOTAL ASSETS		**122,715**	**112,328**

PARENT COMPANY BALANCE SHEET

SEK thousand	Note	2021	2020
	1		
EQUITY AND LIABILITIES			
Equity	19		
Restricted equity			
Share capital		1,203	1,068
Development expenditure fund		3,037	5,123
Non-restricted equity			
Share premium reserve		33,692	-
Option premium		8	698
Retained earnings		103,722	128,547
Profit/loss for the year		-31,149	-27,257
Total equity		**110,513**	**108,179**
Current liabilities			
Trade payables		1,565	1,240
Current tax liabilities		440	462
Liabilities to Group companies		32	459
Other liabilities		772	702
Invoiced but not earned revenue		512	-
Accrued expenses and deferred income	18	8,881	1,286
Total current liabilities		**12,202**	**4,149**
TOTAL EQUITY AND LIABILITIES		**122,715**	**112,328**

PARENT COMPANY CASH FLOW STATEMENT

SEK thousand	Note	2021	2020
	1		
Cash flows from operating activities			
Profit/loss after tax		-31,149	-27,257
Adjustments for non-cash items			
Depreciation and amortization	11,12,13	3,869	3,826
Impairment losses	11	-	508
Tax		-	-
Changes in working capital			
Changes in inventories		-120	361
Changes in current receivables		-2,213	-1,238
Changes in current liabilities		8,053	-5,015
Net cash from operating activities		**-21,560**	**-29,537**
Cash flows from investing activities			
Acquisitions of intangible assets, including capitalized development expenditure	11.12	-2,222	-2,425
Acquisitions of property, plant and equipment	13	-314	-21
Acquisitions/disposals of financial assets		-	242
Acquisitions of subsidiaries	9	-24,891	
Net cash from investing activities		**-27,427**	**-2,204**
Cash flows from financing activities			
New share issue		30,008	-
Transaction expenses attributable to new share issue		-2,307	-
Option premium		8	698
Option repurchase		-352	-
Net cash from financing activities		**27,357**	**698**
NET CASH FLOW FOR THE YEAR		**-21,630**	**-31,043**
Cash and cash equivalents at start of period		88,962	120,005
Cash and cash equivalents at end of period		67,332	88,962
Supplementary cash flow statement disclosures			
Interest received during the year		75	87
Interest paid during the year		-	-1

PARENT COMPANY STATEMENT OF CHANGES IN EQUITY

SEK thousand	SHARE CAPITAL	DEVELOPMENT EXPENDITURE FUND	SHARE PREMIUM RESERVE	SHARE CAPITAL IN PROCESS OF REGISTRATION	SHAREHOLDERS' CONTRIBUTIONS	RETAINED EARNINGS INCLUDING PROFIT/LOSS FOR THE YEAR	TOTAL EQUITY
Opening balance AT 1/1/2017	**162**	**2,334**	**42,381**	**0**	**120**	**-12,062**	**32,936**
2017 loss						-12,675	-12,675
AGM resolution			-42,381		-120	42,501	0
Bonus issue	433					-433	0
New share issue	232		89,881				90,113
Issue expenses			-9,012				-9,012
Options						257	257
Reclassification of options	-54					54	0
Development expenditure		3,574				-3,574	0
Closing balance at 31/12/2017	**773**	**5,908**	**80,869**	**0**	**0**	**14,068**	**101,620**
2018 loss						-17,524	-17,524
AGM resolution			-80,869			80,869	0
New share issue	6		2,334				2,340
Options			111				111
Development expenditure		1,741				-1,741	0
Closing balance at 31/12/2018	**779**	**7,649**	**2,445**	**0**	**0**	**75,672**	**86,546**
2019 loss						-50,336	-50,336
AGM resolution			-2,445			2,445	0
New share issue	281		105,677				105,958
Issue expenses			-10,749				-10,749
Option redemption	8		3,443			-133	3,318
Development expenditure		-308				308	0
Closing balance at 31/12/2019	**1,068**	**7,341**	**98,372**	**0**	**0**	**27,956**	**134,738**
2020 loss						-27,257	-27,257
AGM resolution			-98,372			98,372	0
Options			698				698
Development expenditure		-2,218				2,218	0
Closing balance at 31/12/2020	**1,068**	**5,123**	**698**	**0**	**0**	**101,289**	**108,179**
2021 loss						-31,149	-31,149
AGM resolution			-698			698	0
Non-cash issue	21		6,105				6,126
New share issue	114		29,894				30,008
Issue expenses			-2,307				-2,307
Options			-344				-344
Development expenditure		-2,086				2,086	0
Closing balance at 31/12/2021	**1,203**	**3,037**	**33,348**	**0**	**0**	**72,924**	**110,513**

NOTES

NOTE 1
Accounting policies

Financial statements are prepared in compliance with the Swedish Annual Accounts Act and the general advice of the Swedish Accounting Standards Board in BFNAR 2012:1 (K3). These policies have not been changed since the previous year.

Receivables

Receivables have been recognized at the amount expected to be received.

Other assets, provisions and liabilities

Other assets, provisions and liabilities have been measured at cost unless otherwise specified below.

Revenue recognition

Revenue is measured at the fair value of the amount received or receivable. As a result, the Company recognizes revenue at its nominal value (invoice amount) if the consideration is received in cash or cash equivalents immediately upon delivery. Any discounts provided are deducted.

Work in progress

Revenue from work in progress billed on an ongoing basis is recognized as work is performed and materials are delivered or consumed. Work in progress at a fixed price is recognized using the general rule, which means that revenue and expenses attributable to a project are recognized by reference to the stage of completion at the balance sheet date (percentage-of-completion method). As a result of this, revenue, expenses and profit are recognized in the financial year in which the work is performed.

Property, plant and equipment

Property, plant and equipment is measured at cost less accumulated depreciation and impairment losses. The assets are depreciated on a straight-line basis over their expected useful lives except for non-depreciable land. The useful lives are reassessed at each balance sheet date. The following useful lives are applied:

	Number of years
Equipment, tools, fixtures and fittings	5

Intangible assets

Intangible assets are measured at cost less accumulated amortization and impairment losses. The assets are amortized on a straight-line basis over their expected useful lives.

The useful lives are reassessed at each balance sheet date. Projects in progress are not amortized. Instead they are tested for impairment annually.

Patents are amortized over their term.

	Number of years
Concessions, patents, licenses, trademarks and similar rights	1-20

Capitalization of internally generated intangible assets

Capitalization model

The Company recognizes internally generated intangible assets in compliance with the capitalization model. Under this model, all expenses incurred during the research phase are expensed as incurred. All expenses incurred during the development phase are capitalized if they meet the criteria of BFNAR 2012:1.

Cost includes employee benefit expenses and consulting expenses incurred during development activities along with a reasonable share of relevant overhead costs and any borrowing costs.

Leases

All leases are expensed on a straight-line basis over the term of the lease.

Income tax

Current tax is the income tax for the current financial year on the taxable profit or loss for the year and the share of the income tax of previous financial years that has not yet been recognized.

Current tax is measured at the probable amount using the tax rates and tax laws in force at the balance sheet date.

Receivables and liabilities in foreign currency

Monetary receivables and liabilities in foreign currency have been translated using the exchange rate at the balance sheet date.

Exchange differences arising when monetary items are settled or translated are recognized in profit or loss during the financial year they arise, either as an operating item or as a financial item depending on the underlying transaction.

Estimates and judgements

Management makes estimates and assumptions about the future. These estimates do not always correspond to the actual results. The estimates and assumptions that may lead to risks of substantial adjustments to the carrying amounts of assets and liabilities are primarily those that involve the measurement of capitalized development expenditure. Assets are tested each year for any indication that the value of an asset is lower than its carrying amount. If such an indication is found, the asset's recoverable amount is calculated, which is the lower of the asset's fair value less costs of disposal and its value in use.

NOTE 2
Operating income

The majority of consolidated net sales for 2021 comes from the GARD® product family, totaling SEK 12.1 million. Italian company VitroScreen, which was acquired on 1 November 2021, contributed SEK 3.3 million in the November–December period.

NOTE 3
Intra-Group purchases and sales

Of the Parent Company's total purchases and sales, SEK 704 (2,022) thousand is from intra-Group purchases and SEK 60 (0) thousand from intra-Group sales.

NOTE 4
Leases

The Group has the following operating leases

	Group		Parent Company	
	2021	2020	2021	2020
Paid during the year	1,564	1,398	1,398	1,398
Future operating leases:				
Maturing within one year	2,148	1,395	1,327	1,395
Maturing within 2–5 years	6,110	4,131	2,826	4,131
Maturing later than 5 years	-	-	-	-
Total future leases	**8,258**	**5,526**	**4,153**	**5,526**

The lease payments are for cars, machinery and premises.

NOTE 5
Employees and employee benefit expenses

	Group		Parent Company	
	2021	2020	2021	2020
5.1 Average number of employees				
Men	9	7	9	7
Women	12	11	10	11
Total	**21**	**18**	**19**	**18**
The number of employees in the Group increased by 11 with the acquisition of VitroScreen. These are only counted from 1 November 2021.				
5.2 Number of employees at 31 December				
Men	12	7	9	7
Women	19	10	11	10
Total	**31**	**17**	**17**	**17**
5.3 Expensed salaries and other benefits:				
Salaries and benefits – board and CEO*	4,523	2,650	4,244	2,650
Salaries and benefits – other employees	12,773	8,598	12,099	8,598
Total	**17,296**	**11,248**	**16,343**	**11,248**

NOTE 5
Employees and employee benefit expenses, cont'd

	Group		Parent Company	
	2021	2020	2021	2020
5.4 Social security expenses				
Pension expenses including social security contributions for CEO**	488	360	434	360
Pension expenses including social security contributions for other employees	2,165	2,040	1,911	2,040
Other social security contributions	4,904	3,577	4,862	3,577
Total	**7,557**	**5,977**	**7,207**	**5,977**

*This expense also includes severance pay for the former CEO of SEK 684 thousand.

**This expense also includes pension expenses for the former CEO of SEK 104 thousand.

	Group		Parent Company	
	31/12/2021	31/12/2020	31/12/2021	31/12/2020
Gender distribution among senior executives				
Percentage of men on board	50%	57%	50%	57%
Percentage of men among senior executives	25%	50%	29%	50%

NOTE 6
Agreed remuneration of senior executives

Salaries and other benefits	Base salary / directors' fees	Variable remunera-tion	Other benefits	Pension expenses	Total
Carl Borrebaeck, Chairman	333	-	-	-	333
Laura Chirica, Director	167	-	-	-	167
Anki Malmborg Hager, Director	167	-	-	-	167
Ian Kimber, Director	167	-	-	-	167
Paul Yianni, Director	167	-	-	-	167
Paula Zeilon, Director	167	-	-	-	167
Peter Nählstedt, Director until 18 August 2021	92	-	-	-	92
Total for board	**1,260**	**-**	**-**	**-**	**1,260**
CEO and other senior executives					
Axel Sjöblad, CEO until 18 August 2021*	1,516	-	71	231	1,818
Peter Nählstedt, CEO as of 19 August 2021	769	-	-	118	887
Other senior executives (6 people)	4,670	712	-	755	6,137
Total for senior executives	**6,955**	**712**	**71**	**1,104**	**8,842**
Total for board and senior executives	**8,215**	**712**	**71**	**1,104**	**10,102**

*Axel Sjöblad received a salary and other benefits during the notice period.

Policies

Fees are paid to the board chairman and directors as per AGM resolution. Remuneration of the CEO and other senior executives consists of a base salary and other benefits (company car). Apart from the CEO, the Group's senior executives comprise six employees and one external member.

The 2020 and 2021 AGMs resolved on the fees set out above.

Deliberation and decision-making process

A resolution on the CEO's remuneration and benefits was passed by the SenzaGen Board of Directors. The CEO is preparing a proposal on the remuneration and benefits of other senior executives that will be presented to the board.

Comments on tables

Termination benefits

Both SenzaGen and the CEO shall observe a six month notice period. The CEO is entitled to special severance pay for six months. During the notice period, the CEO is entitled to unchanged fringe benefits, including bonuses. Other senior executives are subject to a notice period of between three and six months in the event of termination by either party. No special severance pay will be due.

Share-based remuneration

No directors or other senior executives hold any share-related remuneration (options, convertibles or the like).

SenzaGen has an employee stock option plan for employees and directors that are not employed by SenzaGen (see Note 18).

The cost of this plan for senior executives and the board was charged to profit or loss in the amount of SEK 0 thousand.

Related party transactions

Via his company Ocean Capital, Board Chairman Carl Borrebaeck has been hired by SenzaGen on a consulting basis to provide scientific and strategic project support for the Company. In 2021, a total of SEK 147 thousand was paid in remuneration to Ocean Capital.

Director Peter Nählstedt was appointed the CEO of SenzaGen in August 2021. During the January–July period, Peter Nählstedt was hired on a consulting basis via his company ReEnergize consulting AB. In 2021, a total of SEK 376 thousand was paid in remuneration to ReEnergize consulting AB.

Director Paul Yianni was hired by SenzaGen on a consulting basis via his company Yianni Consulting. In 2021, a total of SEK 131 thousand was paid in remuneration to Yianni Consulting.

Agreements were based on market terms.

Apart from the remuneration disclosed above, the Company did not engage in any transactions with directors or other related individuals and subsidiaries in 2021.

NOTE 7
Fees and remuneration of Company's auditors

	2021		2020	
	Group	Parent Company	Group	Parent Company
Audit engagement, Mats-Åke Andersson, HLB Auditoriet AB	349	349	268	268
Total	**349**	**349**	**268**	**268**

At the AGM on 5 May 2021, Mats-Åke Andersson was appointed SenzaGen's auditor and Martin Gustafsson was appointed alternate auditor. Mats-Åke Andersson and Martin Gustafsson are authorized public accountants and members of the Institute for the Accountancy Profession in Sweden (FAR).

Audit engagements involve auditing the annual report, the accounting records and the management on the part of the board and CEO, other duties that the Company's auditor is required to perform and providing advice or other assistance prompted by observations during the audit or the performance of other tasks.

NOTE 8
Interest income and interest expenses

Interest income and similar items	Group		Parent Company	
	2021	2020	2021	2020
Interest income	75	76	75	87
Other items	112	0	115	0
Total	**187**	**76**	**190**	**87**

Interest expenses and similar items	Group		Parent Company	
	2021	2020	2021	2020
Interest expenses	-16	-1	-	-1
Other items	-3	-146	-	-146
Total	**-19**	**-147**	**-**	**-147**

NOTE 9
Acquisition analysis

Acquisition analysis VitroScreen s.r.l. (SEK thousand)	2021
Fair value of acquired assets and assumed liabilities	
Intangible assets, excluding goodwill	20,800
Goodwill	13,035
Property, plant and equipment	1,895
Current assets, excluding cash and cash equivalents	5,493
Cash and cash equivalents	1,000
Provisions	-6,106
Non-current liabilities	-1,189
Current liabilities	-3,912
Total fair value of acquired net assets	**31,017**
Acquisition paid for with:	
Cash	24,891
Non-cash issue of shares in SenzaGen AB	6,126
Total	**31,017**

NOTE 10
Goodwill

	Group	
	31/12/2021	31/12/2020
Accumulated cost		
Opening cost	-	-
Acquisition balance	13,245	-
Acquisitions	-	-
Retirements	-	-
Closing accumulated cost	**13,245**	**0**
Accumulated amortization		
Opening amortization	-	-
Amortization for the year	-136	-
Closing accumulated amortization	**-136**	**0**
Closing carrying amount	**13,109**	**0**

NOTE 11
Capitalized development expenditure

	Group		Parent Company	
	31/12/2021	31/12/2020	31/12/2021	31/12/2020
Opening cost	23,362	23,536	23,362	23,536
Acquisition balance	5,653	-	-	-
Acquisitions	31	334	31	334
Retirements	-	-508	-	-508
Closing accumulated cost	**29,046**	**23,362**	**23,393**	**23,362**
Accumulated amortization				
Opening amortization	- 3,462	-1,418	- 3,462	-1,418
Acquisition balance	-94	-	-	-
Amortization for the year	- 2,117	-2,044	-2,117	-2,044
Closing accumulated amortization	**-5,673**	**-3,462**	**- 5,579**	**-3,462**
Accumulated impairment losses				
Opening impairment losses	-12,742	-12,742	-12,742	-12,742
Impairment losses for the year	-	-	-	-
Closing accumulated impairment losses	**-12,742**	**-12,742**	**-12,742**	**-12,742**
Closing carrying amount	**10,631**	**7,158**	**5,072**	**7,158**

Through 2019, SenzaGen received an EU grant for funding development expenditure. These expenses were capitalized as per Company policy and were written down by the same amount because this is funded by the EU grant.

Capitalized research and development expenditure for the year totaled SEK 31 thousand.

Capitalized development expenditure was for the development of new products. The amortization period for intangible assets such as capitalized development expenditure is 5–10 years. The amortization period depends on parameters such as the product life cycle and agreement terms, which should match the period during which the asset gives the Company economic benefits. Amortization begins when development projects are ready for launch.

Disclosure on impairment testing: In the event of an indication that the carrying amount exceeds the recoverable amount, differences are charged to the profit or loss for the period on a rolling basis when they arise. The recoverable amount for capitalized development expenditure is measured based on the expected useful life and volume. This calculation uses estimated future cash flows based on financial forecasts approved by Management and covering the product life cycles. In consideration of the above, Management believes that there is no indication of impairment at 31 December 2021.

NOTE 12
Concessions, patents, licenses, trademarks and similar rights

	Group		Parent Company	
	31/12/2021	31/12/2020	31/12/2021	31/12/2020
Accumulated cost				
Opening cost	9,923	7,833	9,923	7,833
Acquisition balance	15,630	-	-	-
Acquisitions	2,673	2,090	2,191	2,090
Closing accumulated cost	**28,226**	**9,923**	**12,114**	**9,923**
Accumulated scheduled amortization				
Opening amortization	-1,714	-1,130	-1,714	-1,130
Acquisition balance	-65	-	-	-
Amortization for the year	-1,017	-584	-711	-584
Closing accumulated amortization	**-2,796**	**-1,714**	**-2,425**	**-1,714**
Closing carrying amount	**25,430**	**8,209**	**9,689**	**8,209**

NOTE 13
Equipment, tools, fixtures and fittings

	Group		Parent Company	
	31/12/2021	31/12/2020	31/12/2021	31/12/2020
EQUIPMENT				
Accumulated cost				
Opening cost	5,006	5,143	4,992	5,129
Acquisition balance	8,177	-	-	-
Acquisitions	331	21	314	21
Retirement of equipment	-	-158	-	-158
Closing accumulated cost	**13,514**	**5,006**	**5,306**	**4,992**
Accumulated scheduled depreciation				
Opening depreciation	-3,207	-2,361	-3,193	-2,347
Acquisition balance	-6,427	-	-	-
Retirement of equipment	-	158	-	158
Depreciation for the year	-936	-1,004	-848	-1,004
Closing accumulated depreciation	**-10,570**	**-3,207**	**-4,041**	**-3,193**
Closing carrying amount	**2,944**	**1,799**	**1,265**	**1,799**
FIXTURES AND FITTINGS				
Accumulated cost				
Opening cost	963	963	963	963
Acquisition balance	995	-	-	-
Acquisitions	-	-	-	-
Closing accumulated cost	**1,958**	**963**	**963**	**963**
Accumulated scheduled depreciation				
Opening depreciation	-665	-472	-665	-472
Acquisition balance	-799	-	-	-
Depreciation for the year	-208	-193	-193	-193
Closing accumulated depreciation	**-1,672**	**-665**	**-858**	**-665**
Closing carrying amount	**286**	**298**	**105**	**298**
Total closing carrying amount	**3,230**	**2,097**	**1,370**	**2,097**

NOTE 14
Investments in Group companies

Parent Company	2021	2020
Accumulated cost		
Opening cost	84	84
Acquisitions	31,017	-
Closing accumulated cost	**31,101**	**84**
Accumulated impairment losses		
Opening impairment losses	-	-
Impairment losses for the year	-	-
Closing accumulated impairment losses	**0**	**0**
Closing carrying amount	**31,101**	**84**

Name	Headquarters	Company reg. no.	Ownership	Number of shares	Carrying amount
SenzaGen inc	North Carolina	C3870650	100%	1,000 shares	84
VitroScreen S.r.l.	Milan, Italy	1345404158	100%	15,000 quotas	31,017

NOTE 15
Disclosures on share capital and earnings per share

	Number of shares	Quotient value per share	Share capital
Number/quotient value of shares at start of year	21,357,636	0.05	1,067,882
Number/quotient value of shares at end of year	24,064,916	0.05	1,203,246

	2021	2020
Earnings per share		
Earnings per share (SEK)	-1.35	-1.27
Fully diluted earnings per share (SEK)	-1.35	-1.27

Earnings per share is calculated as profit or loss for the year as a percentage of the weighted average of the number of outstanding shares during the year. Per-share data was calculated based on the following numbers of shares.

	2021	2020
Number of outstanding shares (thousands)		
Weighted average during the year	23,162	21,358
At end of year	24,065	21,358

NOTE 16
Pledged assets and contingent liabilities

	2021	2020
For the Group's own liabilities		
Floating charges	1,000	1,000
Contingent liabilities	None	None

Floating charges comprise an unutilized floating charge debenture with Danske Bank.

NOTE 17
Prepaid expenses and accrued income

	Group		Parent Company	
	31/12/2021	31/12/2020	31/12/2021	31/12/2020
Prepaid rent	384	324	322	317
Prepaid insurance	4	209	4	209
Earned but not invoiced revenue	222	-	222	-
Other items	813	689	813	689
Total	**1,423**	**1,222**	**1,361**	**1,215**

NOTE 18
Accrued expenses and deferred income

	Group		Parent Company	
	31/12/2021	31/12/2020	31/12/2021	31/12/2020
Accrued employee benefit expenses	3,298	741	3,139	741
Additional consideration – acquisition	5,113	-	5,113	-
Other items	634	545	629	545
Total	**9,045**	**1,286**	**8,881**	**1,286**

NOTE 19
Equity

At 31 December 2021, the share capital comprised 24,064,916 shares with a quotient value of SEK 0.05.

Each share entitles the holder to one vote and each shareholder with voting rights may vote at the general meeting on the basis of the full number of shares held and represented by him or her without any voting right restrictions. All shares confer equal rights to a share in the Company's assets and profits. The Company itself does not hold any shares.

Convertibles, stock options and similar rights

2020/2023-1 stock option plan
The 2020/2023-1 plan was discontinued in 2021. The options from the plan were repurchased by the Company when CEO Axel Sjöblad resigned his post.

2020/2023-2 stock option plan
The EGM on 18 December 2019 resolved to approve the board's proposal to issue a maximum of 265,000 stock options, as a result of which the Company's share capital may increase by a maximum of SEK 13,250. With the shareholders' preemptive rights waived, current and future senior executives, key personnel and employees of the Company and the Group shall be entitled to subscribe for the stock options.

Each stock option entitles the holder to subscribe for one new share in the Company at an exercise price of SEK 39.68 per share. The stock options may be exercised to subscribe for new shares during the period from 1 November 2022 to 5 January 2023 or the earlier date set out in the option rules.

In the event that all issued stock options are exercised, the number of the Company's shares will increase by 265,000 and the share capital will increase by SEK 13,250.

The maximum dilutive effect of the 2020-2023-2 series is estimated to be no more than 1.24% of the total number of shares and votes in the Company (calculated based on the number of existing shares in the Company without taking into account other outstanding stock options), provided that all offered stock options are issued and exercised.

2020/2024 stock option plan
The EGM on 18 December 2019 resolved to approve shareholder Johan Wennerholm's proposal to issue a maximum of 50,000 stock options, as a result of which the Company's share capital may increase by a maximum of SEK 2,500. With the shareholders' preemptive rights waived, current directors of the Company's board and the Company shall be entitled to the stock options, and the Company shall be entitled and required to, on one or more occasions, transfer stock options to new directors at a price that is no less than the market value of the option calculated using the Black-Scholes pricing model and otherwise subject to the same rules as during the issue.

Each stock option entitles the holder to subscribe for one new share in the Company at an exercise price of SEK 39.68 per share. The stock options may be exercised to subscribe for new shares during the period from 1 November 2023 to 5 January 2024 or the earlier date set out in the option rules.

In addition, the EGM resolved to authorize the Company to transfer to future directors the 2020/2024 series stock options in the Company that are not subscribed by current directors or otherwise use the stock options in order to secure the obligations arising from the 2020/2024 series stock options.

The maximum dilutive effect of the 2020-2024 series is estimated to be no more than 0.23% of the total number of shares and votes in the Company (calculated based on the number of existing shares in the Company without taking into account other outstanding stock options), provided that all offered stock options are issued and exercised.

2021/2024L stock option plan
The AGM on 5 May 2021 resolved to approve the board's proposal to issue a maximum of 587,500 stock options, as a result of which the Company's share capital may increase by a maximum of SEK 29,375.

With the shareholders' preemptive rights waived, employees of the Company and the Group shall be entitled to subscribe for the stock options as follows:

Members of Group Management and key personnel comprising up to nine positions will each be offered to subscribe for a maximum of 50,000 options, altogether comprising a maximum of 450,000 options.

Other employees and consultants considered key personnel in the Group, comprising up to eleven individuals, will each be offered to subscribe for a maximum of 12,500 options, altogether comprising a maximum of 137,500 stock options.

The subscriber is entitled to subscribe for stock options free of charge. The market value of the option has been calculated using the Black-Scholes pricing model, adjusted for barrier conditions to calculate the Company's social security expenses.

The stock options are subject to barrier conditions and cannot be exercised to subscribe for shares until the barrier level has been reached. The barriers are calculated as 158% and 300% of the average of the listed volume-weighted price paid for each trading day as per the Nasdaq First North Growth Market's official price list for shares in the Company during the period from 21 April 2021 to 4 May 2021. Stock options subject to barriers cannot be exercised until the volume-weighted price paid measured per trading day as per the Nasdaq First North Growth Market's official price list for shares in the Company during the share subscription period is higher than the barrier level.

Each stock option entitles the holder to subscribe for one new share in the Company in exchange for cash payment, provided that the provided that the barrier conditions have been met, during the period from 1 June 2024 to 30 September 2024 or the earlier date set out in the option rules.

The maximum dilutive effect of the 2021/2024L series is estimated to be no more than 2.7% of the total number of shares and votes in the Company (calculated based on the number of existing shares in the Company without taking into account other outstanding stock options), provided that all offered stock options are issued and exercised.

Annual report signatures

Carl Borrebaeck
Chairman

Laura Chirica
Director

Paul Yianni
Director

Ian Kimber
Director

Paula Zeilon
Director

Anki Malmborg Hager
Director

Peter Nählstedt
CEO

The annual report and consolidated financial statements were adopted by the board on 24 March 2022.

My auditor's report was submitted on 24 March 2022.

Mats-Åke Andersson
Authorized Public Accountant

SHARE CAPITAL CHANGES

Share capital changes

The table below shows the history of changes in share capital since 2010.

Year	Transaction	Increase in share capital	Increase in number of shares	Total share capital	Number of shares	Quotient value (SEK)
2010	Founding of company			50,000	1,000,000	0.05
2014	Bonus issue	2,500	50,000	52,500	1,050,000	0.05
2015	New share issue	55,660	1,113,200	108,160	2,163,200	0.05
2017	Bonus issue	432,640	-	540,800	2,163,200	0.25
2017	1:5 share split	-	8,652,800	540,800	10,816,000	0.05
2017	New share issue	232,250	4,645,000	773,050	15,461,000	0.05
2018	Option redemption	5,850	117,000	778,900	15,578,000	0.05
2019	Option redemption	7,925	158,500	768,825	15,736,500	0.05
2019	New share issue	281,057	5,621,136	1,067,882	21,357,636	0.05
2020	-	-	-	1,067,882	21,357,636	0.05
2021	New share issue	114,535	2,290,694	1,182,417	23,648,330	0.05
2021	Non-cash issue	20,829	416,586	1,203,246	24,064,916	0.05

Shareholders[1]	Number of shares	Percentage of share capital and votes
Carl Borrebaeck	1,690,000	7.0
Malin Lindstedt	1,614,845	6.7
Ålandsbanken ABP (Finland), Svensk Fillial	1,239,790	5.2
Nordnet Pensionsförsäkring AB	982,333	4.1
Nuami Suad	938,640	3.9
Futur Pension	737,033	3.1
Försäkringsbolaget Avanza Pension	713,016	3.0
Hans Westberg	682,000	2.8
3Rs Management and Consulting	642,372	2.7
Andersson, Jarl Ingvar	641,000	2.7
Total for 10 largest shareholders	**9,881,029**	**41.1**
Other shareholders	14,183,887	58.9
Total	**24,064,916**	**100.0**

[1]The total number of shareholders at 30/12/2021 was 3,196 (3,310) (Euroclear).

SenzaGen stock

SenzaGen's stock has been listed on the Nasdaq First North Growth Market since 21 September 2017.

Ticker symbol: SENZA

ISIN code: SE0010219626
Sector: Health Care

AUDITOR'S REPORT

To the Annual General Meeting of SenzaGen AB (publ)
Company registration number 556821-9207

Report on the annual report
I have performed an audit of the annual report and consolidated financial statements of SenzaGen AB (publ) for the 2021 financial year. The Company's annual report and consolidated financial statements are presented on pages 32–55 of this document.

In my opinion, the annual report and consolidated financial statements have been presented in accordance with the Swedish Annual Accounts Act and, in all material respects, provide a true and fair view of the Parent Company and the Group's financial position at 31 December 2021, financial performance and cash flows for the year in accordance with the Swedish Annual Accounts Act. The directors' report is consistent with the other parts of the annual report and consolidated financial statements.

I therefore recommend the consolidated and Parent Company income statements and balance sheets for adoption by the annual general meeting.

Basis for opinions
I have performed the audit in accordance with the International Standards on Auditing (ISA) and generally accepted auditing practices in Sweden. My responsibility under theses standards is described in more detail in the section entitled Responsibility of the auditor. I am independent of the Parent Company and the Group in accordance with generally accepted auditing practices in Sweden and I have fulfilled our other ethical responsibilities under these requirements.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for our opinions.

Information apart from the annual report and consolidated financial statements
The board of directors and CEO are responsible for this other information. The other information is in the document entitled Annual report for 2021 but does not include the annual report, consolidated financial statements and our auditor's report on these.

My opinion on the annual report and consolidated financial statements does not include this information and I do not provide any opinion on adoption of this other information.

In conjunction with my audit of the annual report and consolidated financial statements, I am responsible for reading the information identified above and considering whether the information is inconsistent with the annual report and consolidated financial statements to a material extent. During this review, I also consider the other knowledge I have obtained during the audit and determine whether the information otherwise seems to contain material misstatements.

If, based on the work performed with respect to this information, I come to the conclusion that this other information contains a material misstatement, then I am required to report this. I have nothing to report in this respect.

Responsibility of the board of directors and CEO
The board of directors and CEO are responsible for the preparation of an annual report and consolidated financial statements that provide a true and fair view in accordance with the Swedish Annual Accounts Act. The board of directors and the CEO are also responsible for such internal control as they determine is necessary to enable the preparation of an annual report and consolidated financial statements that are free of material misstatement, whether due to fraud or error.

During preparation of the annual report and consolidated financial statements, the board of directors and CEO are responsible for assessing the Company and Group's ability to continue business. They provide disclosures, where applicable, on circumstances that could affect the ability to continue business and to apply the going concern assumption. However, the going concern assumption is not applied if the board of directors and CEO plan to liquidate the company, discontinue the business or do not have any realistic alternative to doing this.

Responsibility of the auditor
My objectives are to obtain a reasonable degree of certainty on whether the annual report and consolidated financial statements as a whole are free of material misstatement, whether due to fraud or error, and to submit an auditor's report expressing our opinions. Reasonable certainty is a high degree of certainty, but does not serve as a guarantee that an audit performed in accordance with the ISAs and generally accepted auditing practices in Sweden will always discover a material misstatement if there is one. Misstatements may occur due to fraud or error and may be considered material if they individually or jointly can be reasonably expected to influence the financial decisions made by users on the basis of the annual report and consolidated financial statements.

As part of an audit in accordance with the ISAs, I use my professional judgment and take a professionally skeptical approach throughout the audit. In addition:
- I identify and evaluate the risks of material misstatement in the annual report and consolidated financial statements, whether due to fraud or error, I design and perform audit procedures based in part on these risks, and I obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of failing to discover a material misstatement due to fraud is higher than for a material misstatement due to error, because fraud may include collusion, forgery, deliberate omissions, incorrect information or neglect of internal controls.
- I obtain an understanding of those elements of the company's internal controls that are of significance to my audit in order to design audit procedures that are appropriate in consideration of the circumstances, but not to express an opinion on the effectiveness of internal controls.
- I also evaluate the appropriateness of the accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors and CEO.
- I form an opinion on the suitableness of application of the going concern assumption by the board of directors and CEO in the preparation of the annual report and consolidated financial statements. On the basis of the audit evidence obtained, I also form an opinion as to whether there is any material factor of uncertainty with respect to such events or circumstances as could lead to significant doubt about the Company and Group's ability to continue business. If, in my opinion, there is a material factor of uncertainty, my audit report must call attention to the disclosures in the annual report and consolidated financial statements on this material factor of uncertainty or, if such disclosures are insufficient, I must modify my opinion on the annual report and consolidated financial statements. My opinions are based on the audit evidence obtained up to the date of the auditor's report. However, future events or circumstances may result in a company and group being unable to continue business.
- I evaluate the overall presentation, structure and contents of the annual report and consolidated financial statements, including the disclosures, and whether the annual report provides a true and fair view of the underlying transactions and events.
- I obtain sufficient and appropriate audit evidence on the financial information for the units and business activities within the Group in order to express an opinion on the consolidated financial statements. I am responsible for the control, monitoring and performance of the audit of the consolidated financial statements. I am solely responsible for my opinions.

I must inform the board of directors of the planned scope, focus and timing of the audit. I must also inform the board of directors of significant observations during the audit, including any material internal control deficiencies I have identified.

Report on other legal and regulatory requirements

Opinions
In addition to my audit of the annual report and the consolidated financial statements, I have audited the management of SenzaGen AB (publ) for the 2021 financial year on the part of the Board of Directors and CEO and the proposed appropriation of the Company's profit or loss.

I recommend that the annual general meeting distribute the earnings in accordance with the proposal in the directors' report and discharge the board directors and CEO from liability for the financial year.

Basis for opinions
I have performed the audit in accordance with generally accepted auditing practices in Sweden. My responsibility under theses practices is described in more detail in the section entitled Responsibility of the auditor. I am independent of the Parent Company and the Group in accordance with generally accepted auditing practices in Sweden and I have fulfilled my other ethical responsibilities under these requirements.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinions.

Responsibility of the board of directors and CEO
The board of directors is responsible for the proposed appropriation of the Company's profit or loss. Proposed dividends include an assessment of whether the dividend is justifiable in consideration of the requirements posed by the Company and Group's type of business, scope and risks on the size of the Parent Company and Group's equity, consolidation needs, liquidity and financial position in other respects.

The board of directors is responsible for the Company's organization and for management of the company's affairs. This includes assessing the Company and the Group's financial situation on an ongoing basis and ensuring that the Company's organization is structured in such a way as to ensure other adequate controls on bookkeeping, asset management and the company's financial affairs. The CEO shall take responsibility for day-to-day management in accordance with the guidelines and instructions of the board of directors and shall take the actions necessary to ensure compliance of the Company's bookkeeping with the law and adequate asset management.

Responsibility of the auditor
My objective in my audit of management, and thus our opinion on discharge from liability, is to obtain audit evidence to enable an assessment with a reasonable degree of certainty as to whether any board director or the CEO, in a material respect:
- has taken an action or is guilty of negligence that could incur liability for damages to the Company, or
- has otherwise infringed the Swedish Companies Act, the Swedish Annual Accounts Act or the Company's articles of association.

My objective in my audit of the proposed appropriation of the Company's profit or loss, and thus my opinion on this proposal, is to assess with a reasonable degree of certainty whether the proposal is in harmony with the Swedish Companies Act.

Reasonable certainty is a high degree of certainty, but does not serve as a guarantee that an audit performed in accordance with generally accepted auditing practices in Sweden will always discover actions or negligence that could incur liability to pay damages to the Company, or that the proposed appropriation of the Company's profit or loss is in harmony with the Swedish Companies Act.

As part of an audit in accordance with generally accepted auditing practices in Sweden, I use my professional judgment and take a professionally skeptical approach throughout the audit. My review of management and the proposed appropriation of the Company's profit or loss is mainly based on the my audit of the financial statements. My selection of additional audit procedures to perform is based on our professional judgement in consideration of the risk and materiality. This means that I focus my audit on those actions, areas and circumstances that are material to the business and where divergences and breaches would have particular significance for the Company's situation. I review and assess decisions made, decision-making documentation, actions taken and other circumstances relevant to my opinion on discharge from liability. As the basis for my opinion on the board of directors' proposed appropriation of the company's profit or loss, I have assessed whether the proposal is in harmony with the Swedish Companies Act.

Lund,
24/03/2022

Mats-Åke Andersson
Authorized Public Accountant

CORPORATE GOVERNANCE REPORT

SenzaGen AB (publ) is a Swedish public limited liability company (svenskt publikt aktiebolag). Its headquarters are in Lund and its stock is traded on the Nasdaq First North Growth Market. SenzaGen has around 3,200 shareholders. In addition to the Parent Company, the Group comprises two wholly-owned subsidiaries: SenzaGen Inc (USA) and VitroScreen s.r.l. (Italy)

Responsibility for management and control of SenzaGen is divided between the shareholders at the annual general meeting, the board of directors and the CEO as per the Swedish Companies Act, applicable rules for companies whose stock is listed on the Nasdaq First North Growth Market, the Company's articles of association and the board's internal policy documents.

Annual General Meeting (AGM)

The right of the shareholders to decide on SenzaGen's affairs is exercised at the AGM, which is the Company's highest decision-making body. The AGM decides on several key agenda items, including the appropriation of the Company's retained earnings, the adoption of the income statement and balance sheet, the discharge from liability for the board and CEO, the election of the board and auditors and the board and auditor's fees. Extraordinary general meetings may be held if the board believes such is needed or if the Company's auditors or shareholders with at least 10% shareholdings request such. SenzaGen's principal owners are disclosed under the Changes in share capital heading on page 55.

Four shareholders representing 18% of the total shares and votes in the Company attended SenzaGen's AGM on 5 May 2021 in Lund. All board directors and the Company's auditors were present or represented at the AGM. The AGM resolved to pass all proposals presented by the board and shareholders, including authorization for the board to resolve to issue new shares.

Nomination Committee

The 2019 AGM resolved on policies for SenzaGen's Nomination Committee that are applicable until further notice. The main task of the Nomination Committee is to propose board candidates to the AGM, who are then elected by the AGM. The work of the Nomination Committee starts with reading the evaluation of the board's work commissioned by the board. Then, the Nomination Committee nominates directors and the chairman of the board for the upcoming term. In addition, the Nomination Committee proposes candidates for the position of auditor and presents proposals for the remuneration of the board and auditors.

As per its policies, the SenzaGen Nomination Committee shall comprise the board chairman and one representative from each of the three largest shareholders in terms of the number of votes. The Nomination Committee for the 2022 AGM comprises Malin Lindstedt, Nomination Committee Chair, Erwin Roggen representing 3Rs Management and Consulting, Hans Westberg and the Company's board chairman Carl Borrebaeck. The Nomination Committee had two meetings in 2021 at which minutes were taken.

Board of Directors

The board of directors is responsible for SenzaGen's organization and for management of the Company's affairs. The work of the board is governed by the Swedish Companies Act, the articles of association and the work plan adopted by the board. According to the articles of association, the board shall comprise a minimum of three and a maximum of ten directors with a maximum of five alternates.

The 2021 AGM re-elected Carl Borrebaeck, Ian Kimber, Peter Nählstedt, Laura Chirica, Ann-Christin Malmborg Hager, Paul Yianni och Paula Zeilon. The Company does not have specific committees for auditing and remuneration issues. The full board addresses these issues. Biographies of the directors and their independence can be found on page 60.

Board work and evaluation

The board adopts a formal work plan each year. The work plan is adopted at the first board meeting after the AGM (Statutory Board Meeting) and updated after that as needed. The work plan describes the board's responsibilities and tasks, the division of responsibilities and tasks within the board as well as its working methods, and the division of responsibilities and tasks between the board and the CEO. The currently applicable work plan was adopted on 5 May 2021. The chairman evaluates the work of the board once a year.

Board meetings

The SenzaGen Board of Directors held 15 meetings at which minutes were taken during the year; one was the Statutory Board Meeting and eight were extraordinary meetings. The extraordinary board meetings involved approval of the issue of stock options, the appointment of a new CEO and the acquisition of VitroScreen. At all regular board meetings, the CEO informed directors of the Group's financial position and of significant events in the Company's business. Key agenda items during the year included commercialization strategies, the organization, budget adoption and regulatory matters. Director attendance at the meetings is shown in the table below.

The Company's CEO and CFO regularly attend board meetings. Other executives attend board meetings as needed. The Company's CFO normally serves as secretary at board meetings. The Company's auditor attended at least one of the regular meetings during the year.

Board remuneration

The 2021 AGM set directors' fees for the board chairman at SEK 400,000 and for each of the other directors at SEK 200,000. Board remuneration is described further in Note 6.

Auditor

The Company's auditor, Mats-Åke Andersson, HLB Auditoriet AB, was elected at the 2021 AGM for a term lasting until 2022.

CEO and Management

The CEO is appointed by the board and manages the Company in accordance with the policies and directives adopted by the board. The applicable terms of reference issued to the CEO were adopted by the board on 5 May 2021. The CEO prepares informative and decision-making documentation for board meetings and maintains ongoing dialogue with the board chairman regarding the performance of the Group. The CEO is assisted by a management team consisting of the VPs for each of the Company's functional areas. A more detailed description of the CEO and management team can be found on page 62.

Remuneration of the CEO and other senior executives

The 2020 AGM resolved that the pay of Group Management shall comprise a fixed base salary and variable performance-based remuneration. The variable remuneration includes an individual variable annual fee and may also include a long-term incentive program as a complement. The total remuneration for members of Group Management shall be on market terms. Salaries and other benefits for the CEO and other senior executives are disclosed in Note 6.

Internal control

The board is responsible for keeping an effective system in place for internal control and risk management. The CEO is delegated responsibility for creating a solid foundation for working on these issues. Both Management and managers at various levels of the Company have this responsibility in their respective areas. Powers and responsibilities are defined in guidelines, specifications of responsibilities, policies for approval permissions, and other policies. SenzaGen does not have an internal audit function because the need for such is not justified by the extent and risk exposure of the Company's business.

Director attendance at board meetings

Carl Borrebaeck, chairman	15 of 15
Ian Kimber	12 of 15
Peter Nählstedt*	7 of 15
Laura Chirica	15 of 15
Ann-Christin Malmborg Hager	15 of 15
Paul Yianni	15 of 15
Paula Zeilon	15 of 15

* left the board on 19 August 2021

BOARD OF DIRECTORS

CARL BORREBAECK
Chairman since 2015, director since February 2010.
Born in 1948

Education and experience:
Professor of immunotechnology, DSc major in molecular immunology, MSc in chemical engineering, MSc in life science.

Carl Borrebaeck is a professor at the Department of Immunotechnology and program director of the CREATE translational cancer research center at Lund University. He is an entrepreneur and founded SenzaGen AB and several other life science companies, including Immunovia AB and BioInvent International AB. He is also a founding mentor for the Nordic Mentor Network for Entrepreneurship (NOME), a member of the Royal Swedish Academy of Engineering Sciences (IVA) and former vice-chancellor at Lund University. Carl has won a number of awards for his entrepreneurship and groundbreaking research, including AkzoNobel's Science Prize in 2009 and the Biotech Builder Award in 2017.

Other significant appointments:
Board chairman of Immunovia AB, PainDrainer AB and CB Ocean Capital AB. Board director at Scandion A/S.

Shareholding:
1,698,571 shares (privately and through related parties).

Independence:
Not independent of major shareholders but independent of the Company and Management.

LAURA CHIRICA
Director since 2017.
Born in 1968.

Education and experience:
PhD in biochemistry, MSc in biochemistry and BSc in biotechnology.

Laura Chirica has around 20 years of experience from commercial positions in both startups and multinationals from the life sciences and diagnostics industries and today runs her own consulting business. Her previous positions include Chief Commercial Officer at Immunovia AB, VP Sales and Marketing at Euro Diagnostica AB, director at Purification Technologies Europe Sartorius Stedim, Global Marketing Director at Dako A/S, and Global Marketing Program Manager at GE Healthcare.

Other significant appointments:
Board director at Gradientech AB.

Shareholding:
0.

Independence:
Independent of the Company, Management and major shareholders.

ANKI MALMBORG HAGER
Director since 2019.
Born in 1965.

Education and experience:
PhD in immunotechnology, MSc in chemical engineering, Pharma MBA.

Anki Malmborg Hager has extensive experience from starting life science companies originating from Lund university research. Anki served as CEO of SenzaGen from 2014 to 2019. Her past experience includes CEO of PainDrainer AB, Cantargia AB, XImmune AB and Diaprost AB, and before that, Investment Director at LU Bioscience AB and VP Business Development at Alligator Bioscience AB.

Other significant appointments:
Board director at Avena Partners AB and DiaProst AB.

Shareholding:
383,000 shares.

Independence:
Not independent of the Company and Management. Independent of major shareholders.

IAN KIMBER
Director since 2015.
Born in 1950.

Education and experience:
Emeritus professor of toxicology, PhD and MSc in immunology, BSc in biology.

Ian Kimber serves as Emeritus Professor of Toxicology at the University of Manchester. He has extensive experience from academia, the pharmaceutical, biopharmaceutical and agrochemical industries, and as an independent consultant. Ian has won several awards for his distinguished scientific work and received the OBE in the Queen's Birthday Honours List in 2011. He serves on many expert committees and scientific advisory groups in the UK and internationally.

Other significant appointments:
Emeritus Professor of Toxicology at the University of Manchester.

Shareholding:
1,500 shares.

Independence:
Independent of the Company, Management and major shareholders.

PAULA ZEILON
Director since 2020.
Born in 1962.

Education and experience:
MSc in chemical engineering and business administration

Paula Zeilon has 30 years of management experience from the life science industry including a consulting business in the field of business development and management focusing on the commercialization of new products on international markets. Her past experience includes CEO of Life Science Foresight Institute, CEO of Alligator Biosciences AB, Director Marketing at Dako A/S, Director Marketing at Biotage AB, and management positions with Pharmacia Biotech (now Cytiva).

Other significant appointments:
None.

Shareholding:
6,000 shares. 10,000 stock options.

Independence:
Independent of the Company, Management and major shareholders.

PAUL YIANNI
Director since 2020.
Born in 1959.

Education and experience:
PhD in chemistry.

Paul Yianni runs his own consulting business with a focus on business development, strategy and business coaching. Paul has over 30 years of management experience from the chemicals industry, and he has broad international experience from various technical and commercial functions, including at Dow Corning and Shell Chemicals. His previous positions include CEO of Spolchemie in Czechia and head of M&A at DIC Europe in Germany.

Other significant appointments:
None.

Shareholding:
20,000 shares. 15,000 stock options.

Independence:
Independent of the Company, Management and major shareholders.

Shareholdings at 11 March 2022

SENIOR EXECUTIVES

PETER NÄHLSTEDT
President and CEO.
Employee since 2021, involved with Company since February 2019.
Director 2018-2021.
Born in 1974.

Education and experience:
MSc in chemical engineering, BSc in business administration.

Peter Nählstedt has extensive experience in developing global growth companies in the life sciences industry with a focus on both organic and acquisition-driven growth. In recent years, he had led several international growth projects as a consultant and a board professional. His most recent operational role was as CEO of Probi AB. His past experience includes management positions in strategy, marketing and sales with GE Healthcare Life Science and Trelleborg Marine Systems.

Other significant appointments:
Board chairman at Super Synbiotics AB and DoubleGood AB. Board director at Bio-works AB.

Shareholding:
21,013 shares and 25,000 stock options.

MARIANNE OLSSON
VP Finance.
Employee since 2016.
Born in 1961.

Education and experience:
Certified Financial Manager via FAR.

Marianne Olsson has over 25 years of experience at Lund University where she has served as department economist, financial officer and most recently administrative manager for the Department of Immunotechnology. In addition, Marianne has been a member of the Lund University Faculty of Engineering (LTH) board and a member of the management team and department board at the Department of Immunotechnology.

Other significant appointments:
None.

Shareholding:
114,285 shares and 50,000 stock options.

ANNA CHÉROUVRIER HANSSON
VP Sales & Business Development.
Employee since 2017.
Born in 1973.

Education and experience:
MSc in European affairs in business administration and business law from Lund University, BSc in business administration at Groupe ESC-Reims and Fachhochschule in France and Germany.

Anna has extensive experience in marketing, sales and business development at companies including Camurus, Novo Nordisk, Gambro and DuPont. In addition, Anna has been a partner at Zitha Consulting, where she focused on commercialization strategy in the pharmaceutical industry, and head of life science investments at Invest in Skåne.

Other significant appointments:
Board director at Duearity AB.

Shareholding:
19,153 shares and 65,000 stock options.

Shareholdings at 11 March 2022

TINA DACKEMARK LAWESSON
VP Marketing & Communications.
Employee since 2018.
Born in 1968.

Education and experience:
Bachelor of education (languages) from Malmö Lärarhögskola and journalism studies at Humber College in Canada.

Tina Dackemark Lawesson has long-standing and broad experience in marketing, IR and communications at life science and technology companies in the build-up and growth phases. She has previously held similar positions, including at INVISIO, CellaVision and Enzymatica.

Other significant appointments:
Board director at Medimi AB.

Shareholding:
1,000 shares and 65,000 stock options.

HENRIK JOHANSSON
Chief Scientist.
Employee since 2014.
Born in 1982.

Education and experience:
MSc in biotechnology engineering and PhD in immunotechnology from Lund University.

Henrik Johansson has more than 10 years of research and development experience in the fields of cell and molecular biology. *In vitro* assays for predictive immunotoxicology are his specialty and he is a co-developer of the GARD technology platform, which was first described in detail in his doctoral thesis.

Other appointments:
None.

Shareholding:
526 shares and 10,000 stock options.

ÅSA NYHLÉN
VP Operations.
Employee since 2021.
Born in 1973.

Education and experience:
MSc. in molecular biology from Lund University.

For the past 20 years, Åsa Nyhlén has been responsible for laboratory services in the pharmaceuticals, medical devices and food industries. Åsa has extensive experience of working with international lab partners and building effective and innovative lab organizations. Her past experience includes management positions with Novo Nordisk, Dako and BioGaia.

Other significant appointments:
None.

Shareholding:
6,300 shares and 50,000 stock options.

HELEN OLSSON
VP HR.
Involved with Company since February 2020.
Born in 1965.

Education and experience:
Degree in behavioral science from Lund University and Linnaeus University.

Helen Olsson has over 20 years of experience in organization development, change management, and both operational and strategic HR, including as VP HR at BioGaia.

Other significant appointments:
None.

Shareholding:
5,000 shares.

MARISA MELONI
CEO and founder of VitroScreen S.r.l.
Employed by VitroScreen since 2001.
Born in 1957.

Education and experience:
Pharma D, PhD in biophysics, Contract Professor of Safety Assessment (Italy).

Dr Marisa Meloni has 30 years leadership in promoting *in vitro* science with expertise in developing human relevant safety and efficacy preclinical models based on 3D models.

Other significant appointments:
Board director at VitroScreen S.r.l.

Shareholding:
378,732 shares.

FINANCIAL SUMMARY

	2021	2020	2019	2018	2017
Net sales, SEK thousand	15,422	7,958	2,724	1,997	1,153
Capitalized developed expenditure, SEK thousand	31	334	1,110	1,741	3,575
Profit/loss for the year	-31,346	-27,168	-50,237	-16,090	-13,076
Equity ratio (%)	82	97	94	95	93
Quick ratio, %	332	2,477	2,173	1,307	1,104
Equity, SEK thousand	110,243	107,792	134,211	85,936	101,010
Average number of employees	21	18	22	17	12
Number of employees at year-end, converted to full-time equivalents	31	17	23	19	16
Average number of shares	21,808,849	21,357,636	16,175,772	15,525,563	8,037,933
Number of shares at end of period	24,064,916	21,357,636	21,357,636	15,578,000	15,461,000
Earnings per share, SEK[1]	-1.35	-1.27	-3.11	-1.04	-1.62
Fully diluted earnings per share, SEK[2]	-1.35	-1.27	-3.11	-1.04	-1.62
Equity per share (SEK)	4.58	5.05	6.28	5.52	6.53
Dividend per share, SEK	-	-	-	-	-

[1] Based on average weighted number of outstanding shares.

[2] Dilutive effects are only recognized in cases where they result in lower earnings per share.

Definitions

Equity per share

Reported consolidated equity divided by the number of outstanding shares.

Earnings per share

Profit/loss for the year as a percentage of the average number of outstanding shares.

Fully diluted earnings per share

Profit/loss for the year as a percentage of the average weighted number of shares plus the number of shares added upon full dilution. Dilution occurs in conjunction with stock option plans when the redemption price is less than the current share price.

Equity ratio

Equity as a percentage of total assets.

Quick ratio

Current assets excluding inventories as a percentage of current liabilities.

Financial calendar

5 May 2022 Annual General Meeting

19 August 2022 January-June 2022 Interim Report

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

GLOSSARY AND SOURCES

Allergen
A substance that causes an allergic reaction.

Biomarker
A measurable indicator of a biological condition.

CLP
Classification, Labelling and Packaging. The CLP Regulation contains rules for classifying, labelling and packaging chemical products.

CRO
Contract research organization. A contract lab that provides research services.

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

ESAC
The EURL ECVAM Scientific Advisory Committee.

GHS
Globally Harmonized System of Classification and Labelling of Chemicals. The implementation of this United Nations system Is governed by the CLP in Europe.

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

In vitro
Latin for "in glass". *In vitro* tests are done in test tubes.

KOL
Key opinion leader. An expert whose opinion is respected in a specific industry or field of knowledge.

Contract laboratory
A lab that provides research services.

OECD
Organization for Economic Cooperation and Development, consisting of 36 member countries. The OECD's mission includes creating guidelines for assessing the safety of chemical substances.

Predictive accuracy
The test objects correctly classified as a percentage of the total number of tested objects.

REACH
The European Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals. This regulation requires that all new and existing chemicals be registered and tested to determine whether they could have a negative impact on humans.

Sensitization
The process by which the body develops an (over)sensitivity to something, in other words, an allergy.

Toxicology
A science that deals with poisons and poisoning symptoms, including how drugs and other chemicals can cause various adverse health effects in humans.

Sources

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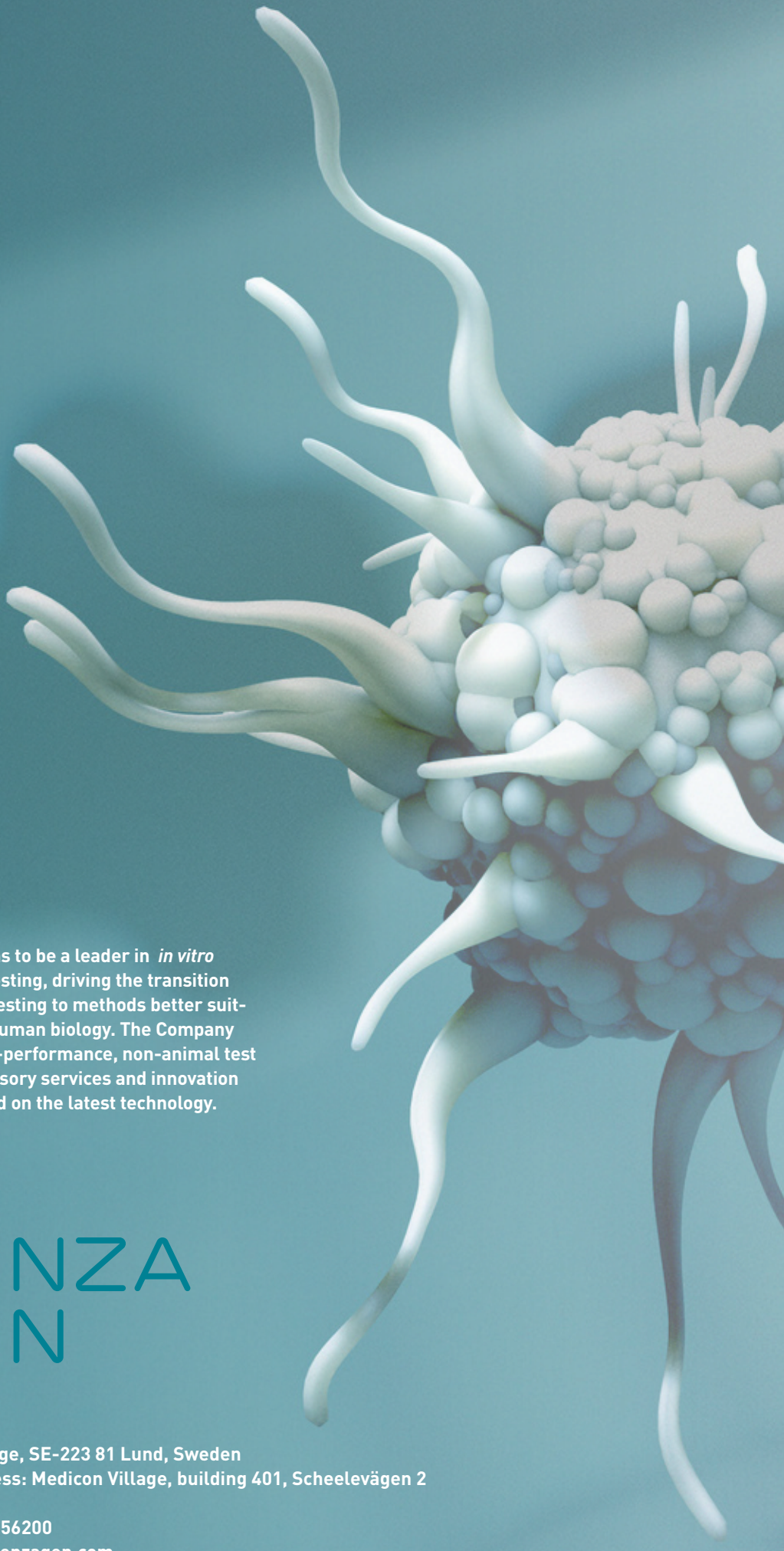

SenzaGen aims to be a leader in *in vitro* science and testing, driving the transition from animal testing to methods better suited to reflect human biology. The Company provides high-performance, non-animal test methods, advisory services and innovation services based on the latest technology.

SENZA GEN

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