



SENZA  
GEN

ANNUAL REPORT

2022

#### Pg. 4. About SenzaGen

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.

#### Pg. 8. Message from the CEO

We have started to see the impact of the OECD approval for GARD<sup>®</sup>skin, which was issued in the end of June and is a key milestone in the Company's growth.

#### Pg. 16. Customer praise for GARD<sup>®</sup>

Interest in our GARD<sup>®</sup> technology has increased, we have received more customer inquiries, and our customers continuously confirm that we are meeting previously unmet testing needs.



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# About SenzaGen

## Business concept

SenzaGen is a corporate group that aims to be an *in vitro* testing leader, driving the transition from animal testing to methods better suited to reflect human biological reactions to toxic substances. We provide human-relevant, high-performance, non-animal test methods and innovation and advisory services based on state-of-the-art technology. With non-animal methods that are more effective, more accurate and less expensive than traditional animal-based methods, we help to reduce the number of laboratory animals.

## Growth strategy

We have a growth strategy centered around continued commercialization of its proprietary GARD® and ORA® test platforms, expansion of its test portfolio and acquisitions of profitable and growing companies with cutting-edge 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. Our market segments are cosmetics, chemicals, medical devices, pharmaceuticals and nutrition/food additives

## Our contribution to a more sustainable world

Our solutions help companies provide products that do not cause allergic or other toxic reactions and also create better production environments for their employees. As a result, we contribute to safe, ethical and more sustainable products reaching the market while also reducing the number of animal tests.

## Our Group companies

**SenzaGen** is an innovative company that has developed GARD®, 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. The company is one of the only Nordic GLP-certified CROs and commands innovative and scientific expertise in skin toxicology, genomics and machine learning. SenzaGen became an operating company in 2014 and now has 21 employees.

Italy-based **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 pre-clinical testing, advisory services, and human 3D tissues and organoid models as a foundation for development and innovation. VitroScreen was founded in 2001 and is a growing and profitable company with 11 employees,

**ToxHub** specializes in toxicological risk assessment and regulatory strategy consulting. Founded in Rome in 2020 by toxicologists with many years of experience from the pharmaceuticals industry, the company has three employees and offers advisory and other services for development projects in a wide variety of industries with expertise in medical devices and pharmacology. Ever since it was started, the company has enjoyed highly fruitful collaboration with VitroScreen.

The SenzaGen Group offers solutions for several parts of the value chain for non-animal testing.

## Market segments



Cosmetics



Chemicals



Medical devices










Pharmaceuticals



Nutrition/  
food additives

## Our non-animal offering

We offer complete solutions for assessing the safety of chemicals in several industries.

PART OF THE VALUE CHAIN	OFFERING	GROUP COMPANIES
<b>Testing strategy</b> Advice and strategies for toxicology safety assessments.	Consulting on how to combine tests	 
<b>In silico</b> Computer-simulated assessment of toxicity in drug candidates, chemicals, medical devices and food additives.	Studies and consulting: QSAR and read-across with expert assessment of results	
<b>In vitro-testing</b> Cell-based identification of toxic properties in drug candidates, chemicals, cosmetics and medical devices.	<ul style="list-style-type: none"><li>• Innovative patented tests: GARD® and ORA®</li><li>• GLP Regulatory toxicology testing</li><li>• Pre-clinical testing</li><li>• Innovation services</li></ul>	 
<b>Regulatory documentation and support</b> Toxicological and pharmacological assessment of results and compilation of regulatory information.	Independent advice for regulatory compliance.	 

# Highlights

Sales increased to SEK 42 million and SenzaGen won its largest order ever. This resulted in 77% organic growth and 171% total growth compared with the previous year.

**APPROVAL of GARD®skin.**  
GARD®skin was approved by the OECD as a test guideline, a regulatory breakthrough giving the Company access to the entire non-animal toxicology market for skin sensitization and creating prospects for increased sales.

SenzaGen strengthened its position within *in vitro* toxicology by acquiring all shares in ToxHub s.r.l., which specializes in toxicology risk assessment and regulatory strategy consulting with specific expertise in medical devices and pharmacology.

Organic

22

million SEK

Net sales

2022

Acquisition

20

million SEK

Net sales

2022

171 %

GROWTH with record-high orders

OECD

APPROVAL of GARD®skin

ACQUISITION

TOXHUB

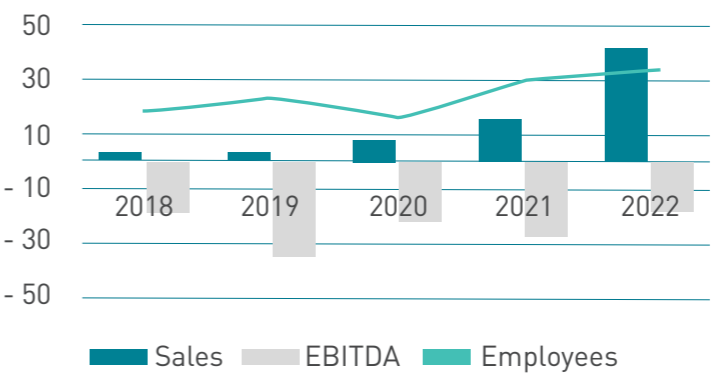
# The year at a glance

- SenzaGen obtained OECD approval for GARD®skin, a key regulatory breakthrough for the GARD® technology.
- SenzaGen’s offering for medical devices was broadened with more tests and toxicology advisory services via realized synergies from the VitroScreen acquisition.
- SenzaGen secured its largest order to date for testing with GARD®skin Dose-Response valued at SEK 4.2 million.
- A new customer, a world leader in the chemicals industry, ordered tests with GARD®skin for a total value of approximately SEK 1 million. The order was both the largest to date for GARD®skin and the largest to date from the chemicals industry.
- Collaboration with the US Research Institute for Fragrance Materials (RIFM) was expanded with a test order valued at SEK 1.5 million for photosensitization with GARD®skin Dose-Response.
- An existing customer in the chemicals industry tested chemicals with GARD®skin and GARD®potency for a value of SEK 0.7 million.
- SenzaGen acquired ToxHub, an Italian company offering toxicology advisory services with specific expertise in medical devices and pharmacology.

## FINANCIAL SUMMARY

SEK million	2022	2021	2020	2019	2018
Net sales	41.8	15.4	8.0	2.7	2.0
Gross margin %	65	61	x	x	x
EBITDA	-15.7	-27.3	-22.7	-34.7	-19.4
Cash and cash equivalents	40.0	69.1	89.3	120.5	56.6

## FINANCIAL PERFORMANCE



## MESSAGE FROM THE CEO

# Technological breakthrough for GARD® and continued strong sales growth

SenzaGen is living up to the high expectations and continues to exhibit strong growth. We are working toward a vision to help the leading companies of the world transition from animal testing to alternative methods with better relevance and performance for humans. This is an issue that is of the utmost importance for both today and tomorrow's society, and as a leader of advanced test systems our company has the prospects to continue growing for many years to come.

### Accelerated growth strategy

The new strategy we launched two years ago aims to accelerate the Company's growth. The strategy, which combines investments in organic and acquisition-driven growth, has already delivered excellent results in the form of significantly higher sales.

We are driving organic growth by selling our GARD® platform for allergen testing directly to world leaders in chemicals, medical devices, cosmetics and pharmaceuticals. We do this with an in-house sales force complemented by strategically selected distributors and license partners. In our sales activities, we prioritize markets and customers with tailwinds for the transition to non-animal testing and with a focus on the best performing solutions. We are continuing to improve our proprietary GARD® platform by obtaining standardized regulatory acceptance and also by developing new tests for customers with a need for advanced technology in the assessment and registration of their products.

The market in which we operate is young and fragmented. A few large CROs offering animal testing and first generation non-animal tests are being followed by a number of small companies with new test methods, advisory services and products. In such a market, we see great potential to drive the consolidation of the smaller market participants, thus building a Group leader in non-animal tests with a complete high-tech offering to help the businesses of the world transition to non-animal testing.

### Our breakout year 2022

2022 was the year SenzaGen achieved a breakthrough both in sales and with its GARD® technology. Our sales increased during the year by as much as 171%, driven by very strong organic growth, 77%, and sales from our two profitable acquisitions. I am very proud of the outstanding performance of our team.

We integrated our first acquisition, VitroScreen, and we have already added value with a combined offering for the medical devices sector, several new orders via cross selling, and R&D collaboration with leading customers combining each company's technology. VitroScreen, which commands expertise in 3D models, preserved its growth rate, clear identity and brand during the integration period and we see great prospects for continuing growth.

SenzaGen achieved the first major regulatory breakthrough for its GARD® technology in mid 2022, obtaining OECD approval for GARD®skin as a standard test method for non-animal skin sensitization. Now results from our method can be used for product filings in all OECD member countries. The Company had been working toward this validation ever since it was founded and it represents a key milestone in the Company's growth. The validation resulted in a significant increase in industry interest and we are working hard and successfully to convert this interest into tests performed with GARD®skin.



“Our sales increased during the year by as much as 171%, driven by very strong organic growth, 77%, and sales from our two profitable acquisitions.”

In addition to GARD®skin, our most recently developed test, GARD®skin Dose-Response, has been leading to success after success with the Company's largest test orders ever. One of the first of its kind, the method makes it possible to replace animal testing when assessing the concentration at which skin-sensitizing substances can be used without causing skin allergies.

We also continued to implement our acquisition strategy by acquiring Italy-based ToxHub in late 2022. ToxHub offers toxicological consulting on test strategies and regulatory services. The acquisition creates an attractive complete solution for customers with both high-tech tests and services to bring a product through the entire approval process. The acquisition is strategically important while also contributing growth and excellent profitability to the Group.

### Favorable outlook

In conclusion, we are pleased with and proud of the past year. Our OECD-approved test, high-tech solutions and advisory services in a market that is continuing to grow from technological, regulatory and ethical drivers give us a very favorable position for continuing high growth. In this market, we also see opportunities to make more acquisitions to continue our journey to deliver a complete non-animal offering with continuing strong growth.

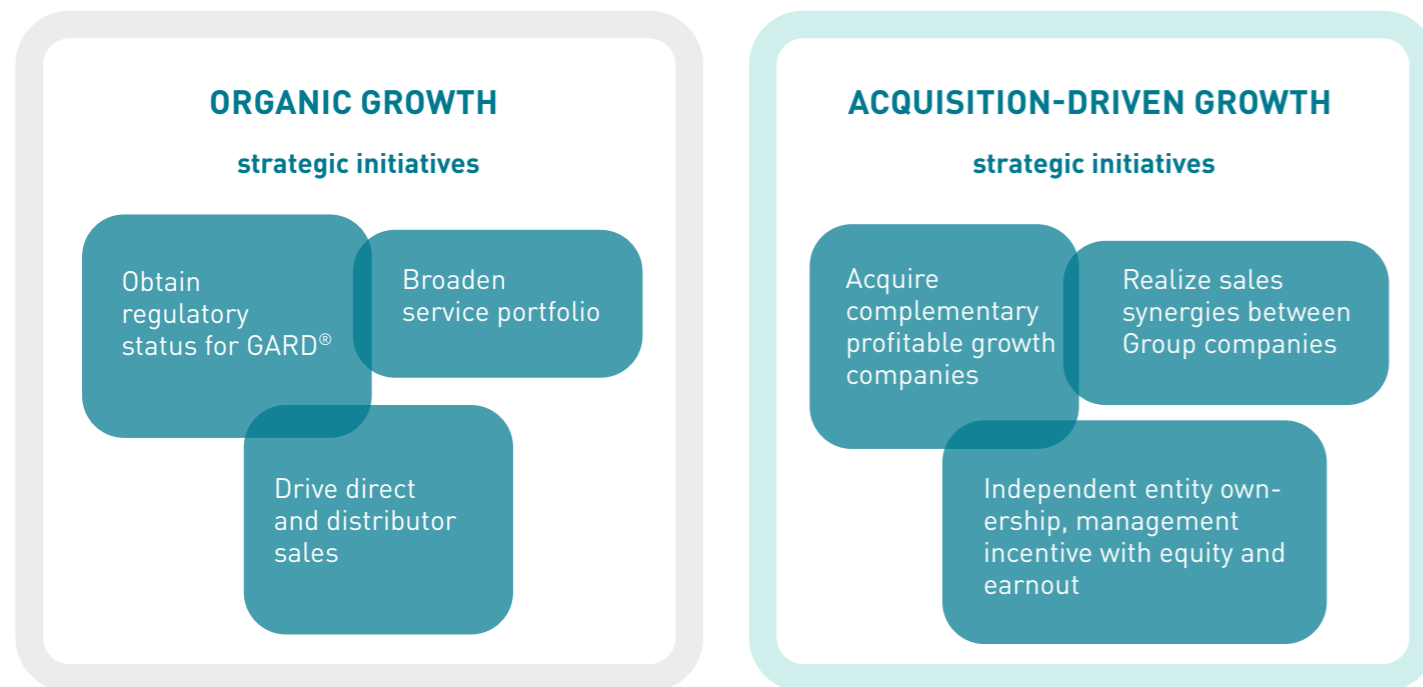
In 2023, we will make the most of our opportunities by continuing to drive organic growth and continuing to invest in innovative tests. We see that continued strong growth combined with effective cost controls will lead the Company closer to profitability.

Last but not least, I would like to thank our dedicated employees and our shareholders who support our vision of a world that has transitioned to new non-animal methods based on the latest technology.

Lund, March 2023

Peter Nählstedt, President and CEO, SenzaGen

# Growth strategy



**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 strategy combines organic growth with acquisition activities.**

## 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, medical devices, pharmaceuticals and nutrition/food additives.

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 engaging in direct contact 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 experience within *in vitro* testing, 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 labs perform tests to evaluate the toxicological properties or preclinical efficacy of various substances. This work also leads to further insights on customer testing needs and provides more knowledge about possibilities for expanding the GARD® and ORA platforms 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 *in vitro* 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.

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

## SenzaGen's 2022 acquisitions

In November, the Group acquired ToxHub, an Italian company specializing in toxicological risk assessment and regulatory strategy consulting. The acquisition amount was EUR 300,000, half of which was paid in shares. In addition to this amount, payment was made for the net cash acquired and additional consideration is contingent on the company's profitability.

## ACQUISITION-DRIVEN GROWTH

### Acquire complementary profitable growth companies

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

### Realize synergies

SenzaGen has a tailored and 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**
- Allocation of tests to specific labs within the Group
- Joint R&D projects

### Independent entity ownership

SenzaGen supports the entrepreneurial spirit, allowing acquired companies to largely continue operating as before but with access to the collective expertise of SenzaGen and the advantages a listed corporate group can offer. The Company believes in strong management incentives to participate in the Group such as equity ownership and additional consideration.

# Trends and drivers

## TRENDS

### Increased focus on alternative tests

The global need for alternative test methods is growing as animal tests are banned and as regulators increasingly advocate for alternative test methods. 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. At the same time, research is progressing, resulting in increased knowledge and new modern methods that deliver results more relevant to human biology. This creates 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 animal tests.

## 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.<sup>1</sup> With these drivers as a basis, SenzaGen 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, making it more cost-effective in most cases. 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.<sup>2,3</sup> 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.<sup>4</sup>

### 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.<sup>5</sup>

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 damaging to 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.<sup>6</sup> This means that no new products that require testing can be developed without the use of an alternative test method. Since then, more countries have followed in the footsteps of the EU, including Norway and individual states in the US and Brazil.<sup>7</sup>

Demands to abandon animal testing are also on the rise in other industries. One of the stipulations is that non-animal methods must be used if such are available. The European Chemicals Agency (ECHA) has collected information on its website about how animal tests can be avoided and how alternatives to animal testing can be used to meet information requirements for REACH registration. In the medical devices industry, the updated international ISO standard 10993-10 advocates the use of alternative methods to animal testing. Additionally, the EU's ongoing implementation of the Medical Device Regulation (MDR) has increased information requirements, resulting in an increase in the number of tests performed, including non-animal tests.<sup>8,9</sup>

The initiatives and legislative proposals of regulators continuously push this debate forward. In the US, the FDA Modernization Act 2.0 banning mandatory animal testing was passed in 2022. The act removes the mandate requiring animal testing in drug production in the US and opens the door to alternative, non-animal methods. The Humane Cosmetics Act, which prohibits animal testing, has also been introduced in the US Congress. This act could lead to a federal ban in addition to about a dozen individual states that have already instituted a ban on animal testing. Collaboration between industry, countries and test developers is also continuing in the context of the OECD, which has 13 ongoing test initiatives up for resolution in the OECD Test Guideline Program in the coming years. At the EU level, the European Partnership for the Assessment of Risks from Chemicals (PARC) is in progress. The €400m initiative aims to develop the next generation of chemical risk assessment methods.

### 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.<sup>10</sup>



INCREASED SOCIAL  
ENGAGEMENT



COST-  
EFFICACY



BETTER  
TEST RESULTS



BANS ON ANIMAL  
TESTING

MARKET

# 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 test methods (*in vitro* methods) have major advantages and are better suited for us humans.

THE *IN VITRO* TOXICOLOGY TESTING MARKET

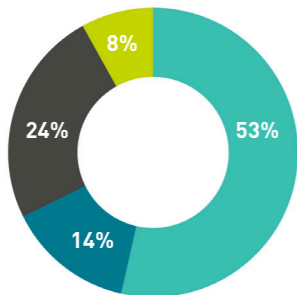
According to market data from Kalorama, the global market for *in vitro* toxicology testing is growing annually by 6.8% and is expected to be worth approximately SEK 80 billion by 2023. This growing market comprises ten subsegments categorized based on the toxicological endpoints they address.

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. Per product category, reagents and equipment account for the largest share of the market followed by CRO services.<sup>11</sup>

*In vitro* toxicology market<sup>11</sup>

Industry segment distribution

- Pharmaceuticals
- Cosmetics
- Chemicals
- Others (food, medical devices, etc)



CURRENT TARGET MARKET

The SenzaGen Group has access to several subsegments of the *in vitro* toxicology testing market. Overall, the addressable market for these segments is expected to be worth about SEK 30 billion in 2023.

Skin sensitization, irritation and corrosion

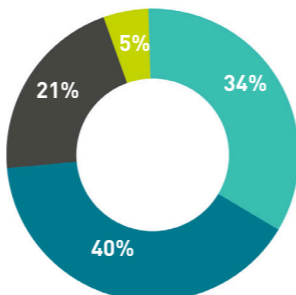
Skin sensitization (skin allergies), combined with irritation and corrosion, is one of the subsegments of *in vitro* toxicology testing and accounts for approximately 6% of the total market. This segment is estimated to be the fastest growing of them all, by 9.5% annually.

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. This endpoint is a part of the Other toxicological endpoints/tests subsegment.

Geographic distribution

- North America
- Europe
- APAC
- RoW



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 new opportunities for the Company.

Foothold in new subsegments via acquisition

The VitroScreen acquisition in 2021 added new subsegments of *in vitro* toxicology testing for SenzaGen and significantly expanded the Company’s potential market. The acquisition strengthened the Company’s position in skin irritation, corrosion and skin sensitization while opening up access to part of the following segments: phototoxicity (toxicity on exposure to sunlight), ocular toxicity (eye toxicity), skin toxicity and other toxicological endpoints/tests. 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.

REGULATORY REQUIREMENTS

To gain access to the entire market, regulators require that the test methods offered are approved for regulatory testing.

The regulations for regulatory testing of chemicals are extensive. Each industry and geographic market usually has different information requirements, guidelines and regulations. Part of the mandate of the

regulators is not only to set requirements for various tests for each endpoint but also to give businesses advice on what animal tests are not necessary. One of the stipulations is that non-animal methods must be used if such are available.

For instance, many EU matters are governed by EU directives and regulations, including the ECHA and EURL-ECVAM, and at the international level, ISO and the OECD play key roles in creating harmonized and integrated regulatory frameworks. In the US, the market is regulated by the FDA and EPA while ICCVAM and NICEATM work to develop and evaluate alternative test methods for animals.

Most regulators also allow the use of test information from non-validated sources that provide sufficient evidence. This means that the results from tests not approved for regulatory use can be used for filings as a weight-of-evidence submission.

In 2022, SenzaGen’s GARD®skin was approved by the OECD as a test guideline for non-animal skin sensitization. The decision enables companies in all OECD member countries to use the test results for regulatory filings in industries including cosmetics and chemicals. The approval gives SenzaGen access to the entire skin sensitization market.

In late 2022, SenzaGen acquired ToxHub, an Italian company offering advisory services for regulatory strategy and non-animal tests. This gives the Group the capability to more effectively help customers with regulator contacts and selection of test methods.

The global market for *in vitro* toxicology testing (2018-2023) (\$, millions)<sup>11</sup>

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

Exchange rate: USD 1 = SEK 9.80

For sources, see page 65

# Customer praise for GARD®

## SONOVIA

The benefits of using GARD®skin Dose-Response in the development of medical device materials and products are seen clearly in Sonova, a leading supplier of hearing solutions. The company's scientific data shows that the test serves as an internal decision-making tool in product development as it provides quantitative information about the concentration at which chemicals that might leach out of materials or medical devices are allergenic.

"An example of scenarios where *in vitro* sensitization methods can, or in my opinion should, be used for medical devices is in development of novel materials and products."

Dr Karla Lienau, Research and Biological Safety Engineer,  
Sonova AG

## CORTEVA AGRISCIENCE

In a new study, Corteva Agriscience studied the capability to test complex mixtures with GARD®skin. The study was compared with data from animals and produced promising results demonstrating that GARD®skin has the potential to replace animal tests while also ensuring human safety.

Investigating the applicability domain of GARD®skin and GARD®potency  
for agrochemical formulations

M. Corvaro, Corteva™ Agriscience Italia, Rome, ITA; A. Forreryd,  
SenzaGen AB, Lund, SWE. Presentation at ICT 2022, Maastricht, NL.

## RIFM

Following successful initial evaluation in 2021, the US Research Institute for Fragrance Materials (RIFM) decided to test more ingredients with GARD®skin Dose-Response, which has been adapted to identify the dose levels at which a fragrance can induce skin allergies when exposed to sunlight (photosensitization).

"We were very excited by the preliminary results we saw with the GARD® Dose-Response adapted for photosensitization. Continuation of this work was the logical next step. Although it is rare, photosensitization is one of the critical human health endpoints RIFM evaluates and having a non-animal assay to assess for photosensitization is key."

Gretchen Ritacco, Principal Scientist, Dermatotoxicology, RIFM

## PORTFOLIO DEVELOPMENT

2022

OECD approval of GARD®-skin.  
Toxicology consulting via ToxHub acquisition.

2021

Studies in advanced 3D tissue models for various indication areas and regulatory approved tests (OECD or ISO) via Vitro-Screen acquisition.

2020

Launch of GARD®skin Dose-Response, a test to define the dose level at which chemicals can cause skin allergies.

2019

Launch of GARD®skin Medical Device, a test to assess whether medical devices can cause allergic reactions on the skin.

2018

Launch of GARD®air, a test to determine whether chemicals can cause allergic reactions in the respiratory tract.

2017

Launch of GARD®skin, a test to determine whether chemicals can cause allergic reactions on the skin.

## IN VITRO OFFERING

# Complete solutions for toxicology safety assessments

With its broad and collective expertise, and a growing portfolio of tests, the SenzaGen Group helps companies test and assess the potential risks and toxicity of chemicals, cosmetics, medical devices and drug candidates. We assess whether the chemicals meet the reliability and safety standards required for approval in the market and provide regulatory and scientific support in contact with relevant regulators. As a trail-blazing company, we also offer customer-specific innovation services and contribute to the development of new *in vitro* methods.

## INNOVATIVE TEST PLATFORMS

### The GARD® platform for skin and respiratory allergies

The incidence of allergic disease is on the rise around the world. Around 20–25 % of the population is estimated to suffer from skin allergies. One source of allergy is exposure to allergenic chemical substances and products. Testing the health impact of chemicals before they are used in consumer products enables replacements with safer chemicals, thus reducing clinical symptoms. Based on the GARD® technology platform, SenzaGen has developed tests that determine whether chemicals 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 animal tests.

### GARD®skin

GARD®skin is used to assess whether chemicals 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.<sup>13</sup> 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. In 2022, the test was approved by the OECD as a 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 level at which a substance can cause skin allergy. With this test, companies in the cosmetics, pharmaceuticals and chemicals industries can obtain information about the concentration at which skin sensitizing substances can be used in consumer products without causing skin allergies, ("the Point of Departure"). This serves as crucial information for prioritization and decision-making in research and development. The test is another application area for GARD®skin, providing quantitative information, and is one of the first of its kind on the market. In 2022, the Company saw continued growing 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. The test is in the process of OECD validation.

GARD®air

GARD®air is used to assess whether chemicals in product candidates can cause respiratory allergies. The test is the first on the market, and it is recommended for use during the research and development process. Evaluating whether chemicals can 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

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

Via VitroScreen the Group 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

Testing new products in the microbiome domain requires specific tools that give researchers the capability to study how both hosts and microorganisms react when they are exposed to chemicals, changed external conditions or other variables. The SenzaGen Group offers colonized 3D tissue models, models made of human tissue that have been colonized by microorganisms, to study host-microbe interaction. The method is useful for new products produced in the nutrition and pharmaceuticals industries. Additionally, the tests are offered without 3D models to measure prebiotic and antibacterial efficacy and biofilm formation.

RAPIDLY GROWING PORTFOLIO OF GLP REGULATORY TOXICOLOGY TESTS

Methods approved as OECD guidelines

The SenzaGen Group offers several regulatory *in vitro* tests, meaning tests that are approved by the OECD, 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 laboratories in Lund and Milan design and perform both GLP and non-GLP studies.

Regulatory toxicology test portfolio

Endpoint	Test
Skin sensitization, GARD®	OECD TG 442E
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

Via VitroScreen, the Group 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

For drugs and medical devices, there is a need to identify or rule out a pharmacological, immunological or metabolic mechanism of action. 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.

IN SILICO STUDIES

Computer-simulated assessments of toxicity, referred to as *in silico* studies, are performed early on in the development process to determine whether drug candidates, chemicals, medical devices or food additives are viable for testing in higher model systems (*in vitro* or *in vivo*) without causing toxicity. By performing this screening early on, problematic product candidates can be filtered out at an early stage and resources can be focused on evaluating the best chemicals. Via ToxHub, we provide advice on *in silico* studies and can also perform them via partners.

ADVISORY SERVICES

Expert toxicology support

With the SenzaGen Group as an advisory partner, companies can make the right decision early on in their development projects and then receive guidance towards a product filing. Independent experts at VitroScreen och ToxHub provide advice on how necessary and scientifically significant tests should be combined for each customer project. The test models are based on regulatory requirements but are also tailored to the specific preferences of each customer. At VitroScreen, we offer an integrated solution with advisory services and *in vitro* tests. With advice, preparation of regulatory documentation and support in contacts with relevant regulators, companies are assisted in meeting the regulatory requirements on the road to a product filing. Demand for advisory services has increased significantly over the past year as a result of the implementation of new legislation for medical devices.

INNOVATION SERVICES

Tailored solutions

The SenzaGen Group leverages its experience and knowledge in the fields of *in vitro* toxicology and preclinical testing to offer tailored solutions based on the patented technology platforms, GARD® and ORA®, and based on 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. For instance, in 2022, the Group pooled its expertise in 3D cell models and data analysis based on the genomics platform in a number of development projects conducted with customers. These development projects gave customers more information-rich and quantitative material, which meets a clearly emerging need for more mechanistic information.

## PLATFORMS

# Technology for innovation

Investing in developing better methods than animal models is crucial for both ethical and scientific reasons. By offering groundbreaking innovations that are better suited to reflect human biological reactions, SenzaGen is leading developments away from animal tests.

SenzaGen leverages its technical and interdisciplinary expertise in genomics, machine learning, organoids and human 3D tissue models to meet the needs of society for more powerful methods to replace animal testing.

### **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%.

<sup>14,15</sup>

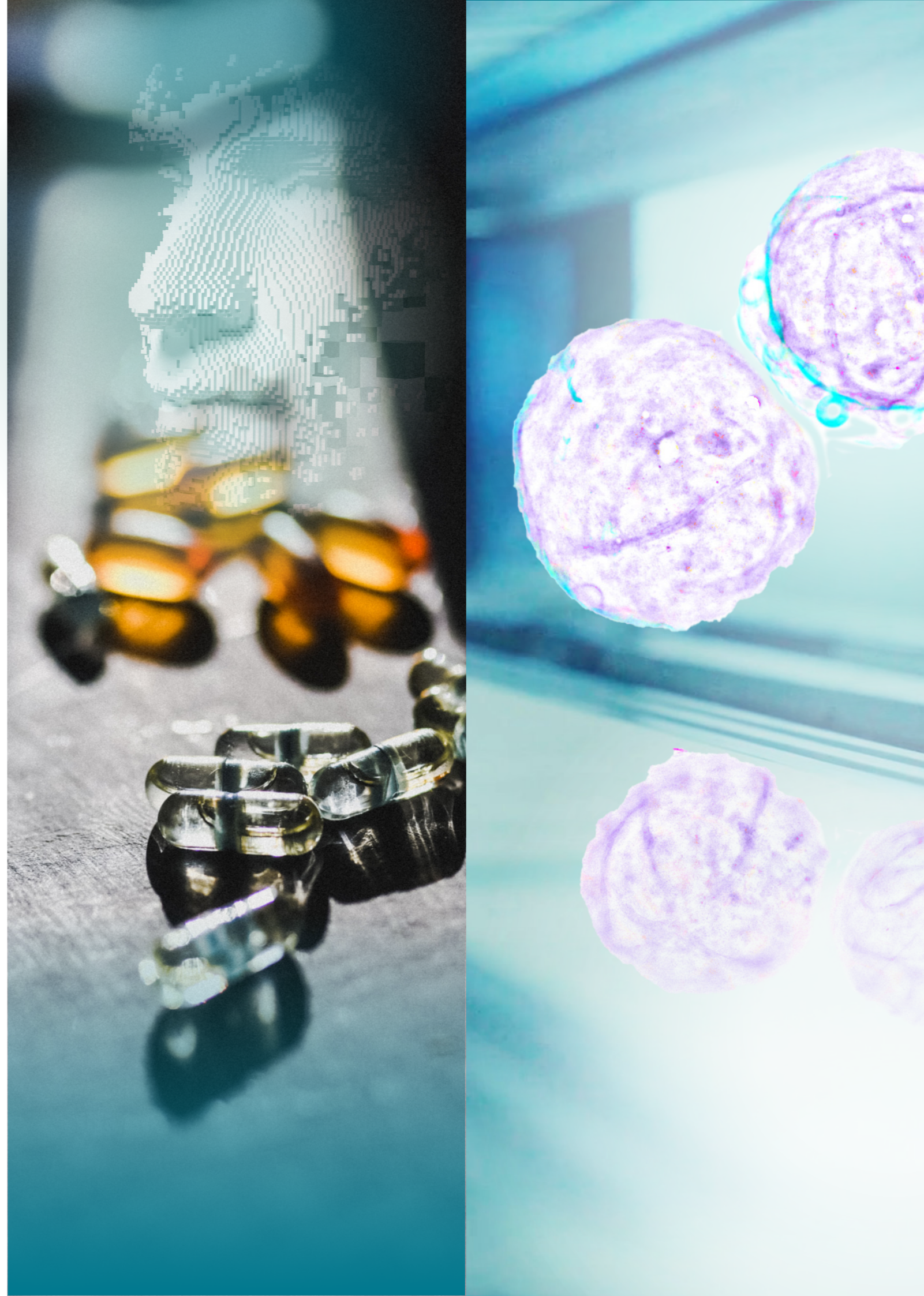
### **The ORA® platform for organ toxicity and efficacy**

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 better and safer results 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 used. 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*.

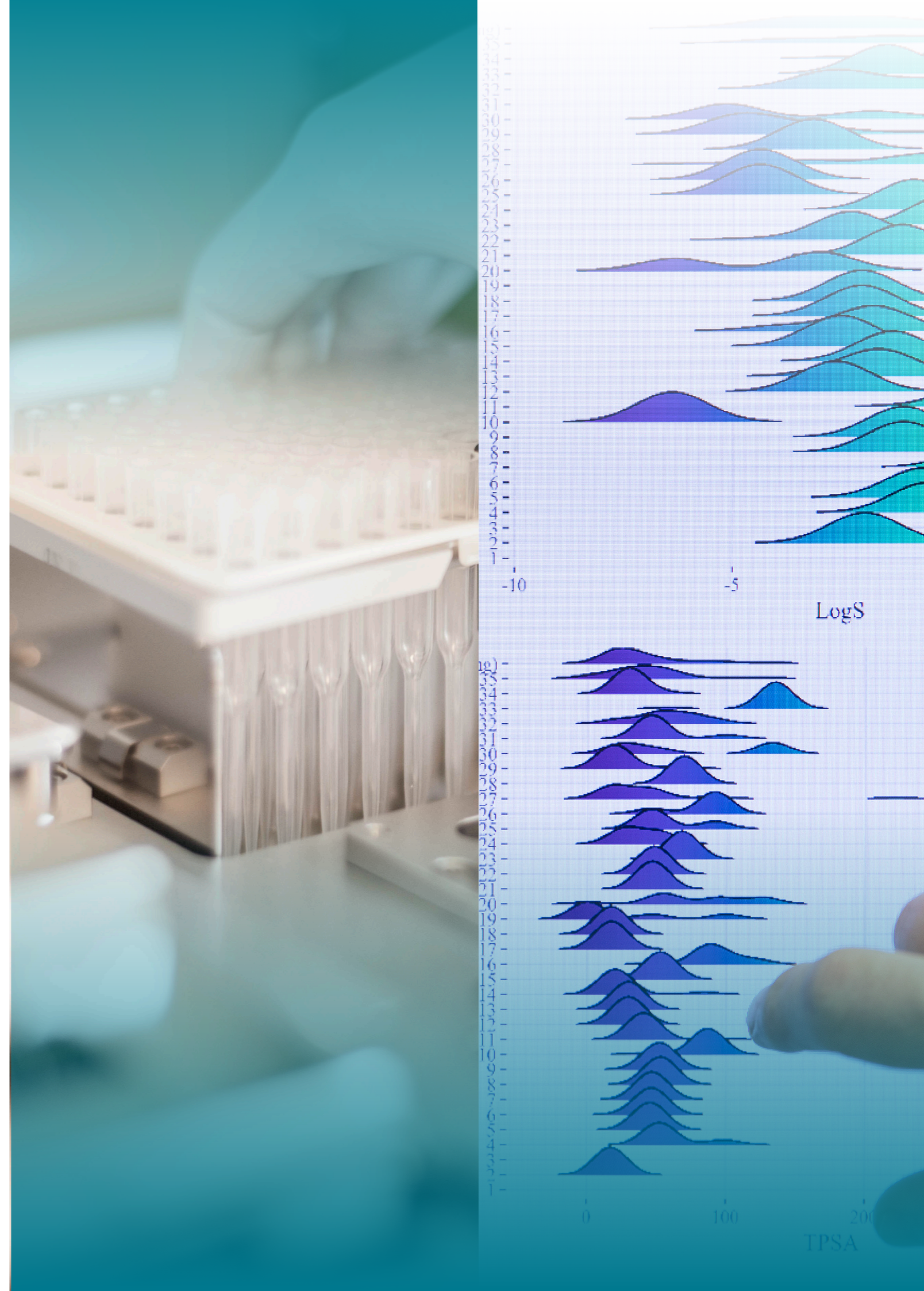
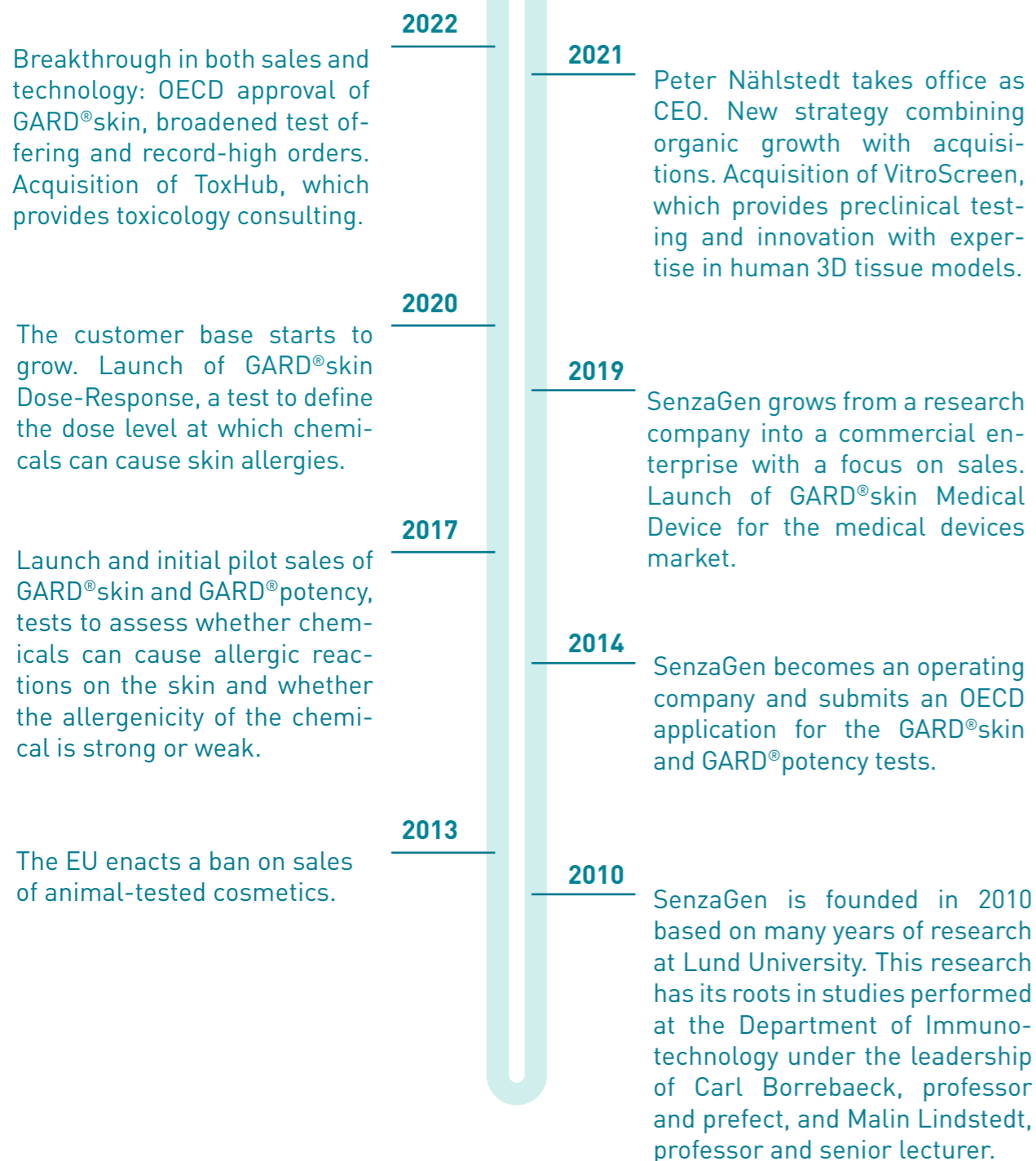
### **New customer-specific development projects**

SenzaGen and VitroScreen pool their expertise in the development of completely new innovative solutions applying 3D-cell models and data analysis based on SenzaGen's genomics platform. Customers are estimated to have an increased need to be able to identify mechanisms of action, and this requires more detailed and data-rich information. This can be achieved by combining 3D models and genomics analysis. The Group has already conducted several pilot studies in collaboration with leading cosmetics and pharma companies.



## SENZAGEN'S

# History



# 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.

## 2022 progress

In 2022, SenzaGen's headquarters continued to develop and systematically implement the employee policies relevant in consideration of the Company's size, business and statutory requirements. The basis for this was laid by the situation analysis performed in 2021 and systematic work environment efforts. For instance, the Company created relevant policies for remote working, travel, salaries, and for pensions and insurance.

## 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, the Company has frameworks in place that are based on the fundamental values expressed in the UN Global Compact's ten principles, including a code of conduct. 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. SenzaGen also expects business partners to apply similar standards and principles in their operations and act in accordance with agreed contracts.

In addition to these policies, the Company also has separate anti-corruption directives. 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.

At VitroScreen's laboratory in Milan, a project was in progress during the year to implement a quality management system compliant with ISO 9001 and ISO 13485.

## 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 its Swedish lab operations follow 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.

Since 2021, the Company's headquarters at Medicon Village in Lund, Sweden has been connected to the science park's new technical energy solution, ectogrid. As a result, the buildings in the area 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

The SenzaGen Group 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 Defined Approaches on Skin Sensitization.
- 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 the SenzaGen Group, 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.

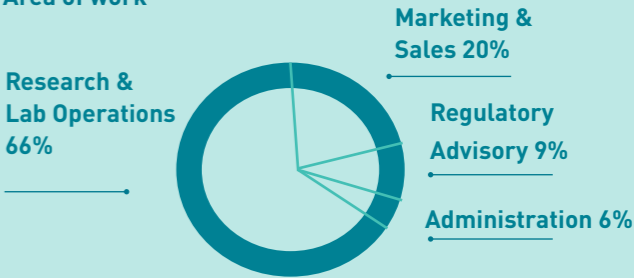
To promote health, SenzaGen offers its employees in Lund a wellness allowance, health checkups and disability insurance benefits. Questions of well-being, job satisfaction and perceived health situation are taken up during the Company’s annual performance reviews. The rate of absence due to illness is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

Four new employees were added during the year, three of which via the ToxHub acquisition. At the end of the year, the number of Group employees was 35 (31), 24 were women (19) and 11 were men (12).

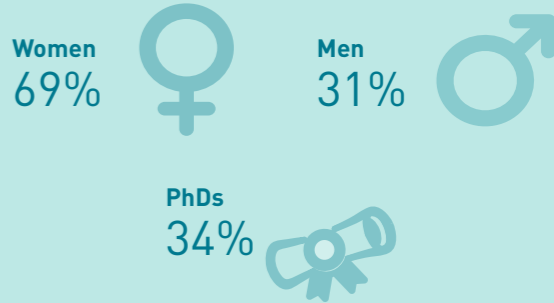


THE GROUP

Area of work



Gender and education



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 2022 financial year.

Business

SenzaGen aims to be an *in vitro* testing leader, driving the transition from animal testing to methods better suited to reflect human biological reactions to toxic substances. 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. Italy-based CRO VitroScreen has been a Group company since 2021 and ToxHub since 2022. The latter is active in toxicological risk assessment and regulatory strategy consulting.

Group

SenzaGen is a corporate group consisting of SenzaGen AB, the Parent Company headquartered in Lund, and three wholly-owned subsidiaries, SenzaGen North America Inc (North Carolina, USA), VitroScreen S.r.l. (Milan, Italy) and ToxHub s.r.l. (Rome, Italy). The Group's employees primarily work at the Parent Company in Lund and the subsidiaries 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 35 (31) at year-end. 24 (19) of the employees were women and 11 (12) were men. More information is provided under the section about employees in the sustainability report on page 30-31.

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 GARD® technology 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 2022, 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 OECD validation process for GARD®skin where documentation work and supplementary studies were performed to support the application. The Company obtained approval from the OECD in June 2022.

Financial performance

Consolidated net sales for the year amounted to SEK 41.8 (15.4) million, a 171 percent year-on-year increase. Organic sales accounted for SEK 21.5 (12.2) million, corresponding to a 77% increase, and acquired sales contributed SEK 20.3 (3.3) 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 -24.9 (-31.5) million.

Operating expenses for the year totaled SEK 68.0 (47.5) 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.

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 2.0 (2.3) million, with patents and trademarks accounting for SEK 2.0 (2.3) million of this amount. Capitalized expenditure for in-house development projects totaled SEK 0 (31) thousand.

The Group's cash and cash equivalents at the end of the year totaled SEK 40.0 (69.2) million.

Net cash from operating activities for the year was SEK -16.0 (-21.0) million. Total net cash flow for the year amounted to SEK -29.2 (-20.2) thousand.

During the year, 637,500 stock options were subscribed by employees under the employee incentive programs adopted by the 2022 AGM.

The 2022 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 2022 AGM.

Under the 2022 AGM authorization, a non-cash issue of 123,409 shares was conducted, which increased the share capital by SEK 6,170.45.

Significant events during the year

28 April, 2022. SenzaGen's sales for January–March 2022 increased by over 370% to SEK 9.0 million due to very strong organic and acquisition-driven growth.

22 June, 2022. SenzaGen won an order for non-animal testing with GARD®skin Dose-Response from a major international industry organization. Valued at SEK 4.2 million, the order was the largest for GARD® tests to date, confirming the technology's strengths and many unique application areas.

30 June, 2022. SenzaGen obtained OECD approval for GARD®skin, a regulatory breakthrough giving the Company access to the entire non-animal toxicology market for skin sensitization and creating prospects for increased sales.

26 Oct. 2022. SenzaGen announced continued very strong sales growth in Q3 2022. Sales increased by a factor of three year-on-year to SEK 9.0 million, driven by strong organic growth with new and returning major global customers combined with acquisition growth.

11 Nov. 2022. SenzaGen strengthened its position within *in vitro* toxicology by acquiring all shares in ToxHub s.r.l., which specializes in toxicology risk assessment and regulatory strategy consulting with specific expertise in medical devices and pharmacology.

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 growth strategy, which combines organic growth with acquisition activities, is expected to continue 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	72,404,865
Share premium reserve	37,579,928
Profit/loss for the year	-21,356,557
The board proposes that the following amount be carried forward	-88,628,235

Dividend

The board proposes no dividend for the 2022 financial year.

## CONSOLIDATED INCOME STATEMENT

SEK thousand	Note	2022	2021
	1		
<b>Operating income</b>			
Net sales	2	41,770	15,422
Cost of goods sold		-14,434	-5,969
<b>Gross profit/loss</b>		<b>27,336</b>	<b>9,453</b>
<b>Operating expenses</b>	4,5,6,7,8		
Selling expenses		-21,609	-21,234
Administrative expenses		-17,418	-15,550
Research and development expenditure		-8,985	-3,874
Acquisition-related expenses		-4,921	-293
Other operating income		1,189	542
Other operating expenses		-703	-577
<b>Operating profit/loss</b>		<b>-25,111</b>	<b>-31,533</b>
<b>Profit/loss from financial items</b>			
Interest income and similar items	8	338	187
Interest expenses and similar items	8	-189	-19
<b>Profit/loss after financial items</b>		<b>-24,962</b>	<b>-31,365</b>
<b>Profit/loss before tax</b>		<b>-24,962</b>	<b>-31,365</b>
Tax on profit/loss for the year		50	19
<b>PROFIT/LOSS FOR THE YEAR</b>		<b>-24,912</b>	<b>-31,346</b>
Share of profit/loss attributable to Parent Company share-holders		-24,912	-31,346
Share of profit/loss attributable to minority interests			-

## CONSOLIDATED BALANCE SHEET

SEK thousand	Note	2022	2021
	1		
<b>ASSETS</b>			
<b>Non-current assets</b>			
<i>Intangible assets</i>			
Goodwill	9, 10	21,647	13,109
Capitalized development expenditure	11	7,759	10,631
Concessions, patents, licenses, trademarks and similar rights	12	30,348	25,430
<b>Total intangible assets</b>		<b>59,754</b>	<b>49,170</b>
<i>Property, plant and equipment</i>			
Equipment, tools, fixtures and fittings	13	2,575	3,230
<b>Total property, plant and equipment</b>		<b>2,575</b>	<b>3,230</b>
<i>Financial assets</i>			
Non-current receivables		-	-
<b>Total financial assets</b>		<b>0</b>	<b>0</b>
<b>Total non-current assets</b>		<b>62,329</b>	<b>52,400</b>
<b>Current assets</b>			
Inventories		3,614	3,201
<b>Total inventories</b>		<b>3,614</b>	<b>3,201</b>
<b>Current receivables</b>			
Trade receivables		9,094	6,269
Other receivables		554	1,348
Earned but not invoiced revenue	17	2,752	222
Prepaid expenses and accrued income	17	1,635	1,201
<b>Total current receivables</b>		<b>14,035</b>	<b>9,040</b>
Cash and bank balances		39,976	69,164
<b>Total current assets</b>		<b>57,625</b>	<b>81,405</b>
<b>TOTAL ASSETS</b>		<b>119,954</b>	<b>133,805</b>

## CONSOLIDATED BALANCE SHEET

SEK thousand	Note	2022	2021
	1		
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>	19		
Share capital		1,209	1,203
Other contributed capital		921	2,739
Retained earnings		108,897	136,953
Profit/loss for the year		-24,912	-31,346
Translation differences		3,586	694
<b>Total equity attributable to Parent Company shareholders</b>		<b>89,701</b>	<b>110,243</b>
<b>Non-current liabilities</b>			
Liabilities to credit institutions		1,207	714
<b>Total non-current liabilities</b>		<b>1,207</b>	<b>714</b>
<b>Current liabilities</b>			
Trade payables		4,420	3,135
Other provisions		7,321	6,235
Current tax liabilities		411	440
Other liabilities		3,506	2,447
Invoiced but not earned revenue		99	1,546
Accrued expenses and deferred income	18	13,289	9,045
<b>Total current liabilities</b>		<b>29,046</b>	<b>22,848</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>119,954</b>	<b>133,805</b>

## CONSOLIDATED CASH FLOW STATEMENT

SEK thousand	Note	2022	2021
	1		
<b>Cash flows from operating activities</b>			
Profit/loss after tax		-24,912	-31,346
Adjustments for non-cash items			
Depreciation and amortization	10,11,12,13	9,420	4,268
Impairment losses	11	-	-
Foreign currency translation, unrealized		225	6
Tax		-500	-39
<b>Changes in working capital</b>			
Changes in inventories		-158	45
Changes in current receivables		-4,190	-1,468
Changes in current liabilities		4,051	7,554
Deferred tax liabilities		-7	-
<b>Net cash from operating activities</b>		<b>-16,071</b>	<b>-20,980</b>
<b>Cash flows from investing activities</b>			
Acquisitions of intangible assets, including capitalized development expenditure	10,11,12	-1,982	-2,334
Acquisitions of property, plant and equipment	13	-607	-331
Acquisitions/disposals of subsidiaries	9	-13,041	-23,890
Acquisitions/disposals of financial assets		2,193	-
<b>Net cash from investing activities</b>		<b>-13,437</b>	<b>-26,555</b>
<b>Cash flows from financing activities</b>			
New share issue		-	30,008
Transaction expenses attributable to new share issue		-42	-2,306
Option premium		-	8
Option repurchase		-	-352
Change in non-current liabilities to credit institutions		73	-68
<b>Net cash from financing activities</b>		<b>31</b>	<b>27,290</b>
<b>NET CASH FLOW FOR THE YEAR</b>		<b>-29,477</b>	<b>-20,245</b>
Cash and cash equivalents at start of period		69,164	89,343
Translation difference on cash and cash equivalents		289	66
Cash and cash equivalents at end of period		39,976	69,164
<b>Supplementary cash flow statement disclosures</b>			
Interest received during the year		171	75
Interest paid during the year		-28	-16

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

SEK thousand	SHARE CAPITAL	OTHER CONTRIBUTED CAPITAL	ACCUMULATED LOSS	TOTAL EQUITY
<b>Opening balance at 1/1/2018</b>	<b>773</b>	<b>123,681</b>	<b>-23,445</b>	<b>101,010</b>
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
<b>Closing balance at 31/12/2018</b>	<b>779</b>	<b>126,126</b>	<b>-40,970</b>	<b>85,936</b>
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
<b>Closing balance at 31/12/2019</b>	<b>1,068</b>	<b>224,364</b>	<b>-91,222</b>	<b>134,211</b>
2020 loss			-27,168	-27,168
Options		698		698
Foreign currency effects			51	51
<b>Closing balance at 31/12/2020</b>	<b>1,068</b>	<b>225,062</b>	<b>-118,339</b>	<b>107,792</b>
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
<b>Closing balance at 31/12/2021</b>	<b>1,203</b>	<b>258,410</b>	<b>-149,371</b>	<b>110,243</b>
2022 loss			-24,912	-24,912
Non-cash issue	6	1,623		1,629
Issue expenses		-42		-42
Foreign currency effects			2,783	2,783
<b>Closing balance at 31/12/2022</b>	<b>1,209</b>	<b>259,991</b>	<b>-171,500</b>	<b>89,701</b>

## PARENT COMPANY INCOME STATEMENT

SEK thousand	Note	2022	2021
	1		
<b>Operating income</b>			
Net sales	2.3	21,501	12,164
Cost of goods sold		-7,430	-4,570
<b>Gross profit/loss</b>		<b>14,071</b>	<b>7,594</b>
<b>Operating expenses</b>	4,5,6,7,8		
Selling expenses		-20,534	-21,143
Administrative expenses		-12,041	-14,632
Research and development expenditure		-3,543	-3,035
Other operating income		1,150	454
Other operating expenses		-699	-577
<b>Operating profit/loss</b>		<b>-21,596</b>	<b>-31,339</b>
<b>Profit/loss from financial items</b>			
Interest income and similar items	8	356	190
Interest expenses and similar items	8	-117	0
<b>Profit/loss after financial items</b>		<b>-21,357</b>	<b>-31,149</b>
Tax on profit/loss for the year		-	-
<b>PROFIT/LOSS FOR THE YEAR</b>		<b>-21,357</b>	<b>-31,149</b>

## PARENT COMPANY BALANCE SHEET

SEK thousand	Note	2022	2021
	1		
<b>ASSETS</b>			
<b>Non-current assets</b>			
<i>Intangible assets</i>			
Capitalized development expenditure	11	2,941	5,072
Concessions, patents, licenses, trademarks and similar rights	12	10,774	9,689
<b>Total intangible assets</b>		<b>13,715</b>	<b>14,761</b>
<i>Property, plant and equipment</i>			
Equipment, tools, fixtures and fittings	13	861	1,370
<b>Total property, plant and equipment</b>		<b>861</b>	<b>1,370</b>
<i>Financial assets</i>			
Investments in Group companies	14	46,103	31,101
Receivables from Group companies		1,252	1,085
<b>Total financial assets</b>		<b>47,355</b>	<b>32,186</b>
<b>Total non-current assets</b>		<b>61,931</b>	<b>48,317</b>
<b>Current assets</b>			
Inventories		973	1,185
<b>Total inventories</b>		<b>973</b>	<b>1,185</b>
<b>Current receivables</b>			
Trade receivables		3,405	3,144
Other receivables		1,343	1,376
Earned but not invoiced revenue	17	2,752	222
Prepaid expenses and accrued income	17	1,428	1,139
<b>Total current receivables</b>		<b>8,928</b>	<b>5,881</b>
Cash and bank balances		36,242	67,332
<b>Total current assets</b>		<b>46,143</b>	<b>74,398</b>
<b>TOTAL ASSETS</b>		<b>108,074</b>	<b>122,715</b>

## PARENT COMPANY BALANCE SHEET

SEK thousand	Note	2022	2021
	1		
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>	19		
<i>Restricted equity</i>			
Share capital		1,209	1,203
Development expenditure fund		906	3,037
<i>Non-restricted equity</i>			
Share premium reserve		37,581	33,692
Option premium		-	8
Retained earnings		72,405	103,722
Profit/loss for the year		-21,357	-31,149
<b>Total equity</b>		<b>90,744</b>	<b>110,513</b>
<b>Current liabilities</b>			
Trade payables		2,584	1,565
Current tax liabilities		411	440
Liabilities to Group companies		405	32
Other liabilities		751	772
Invoiced but not earned revenue		99	512
Accrued expenses and deferred income	18	13,080	8,881
<b>Total current liabilities</b>		<b>17,330</b>	<b>12,202</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>108,074</b>	<b>122,715</b>

## PARENT COMPANY CASH FLOW STATEMENT

SEK thousand	Note	2022	2021
	1		
<b>Cash flows from operating activities</b>			
Profit/loss after tax		-21,357	-31,149
Adjustments for non-cash items			
Depreciation and amortization	11,12,13	3,864	3,869
Impairment losses	11	-	-
Tax		-	-
<b>Changes in working capital</b>			
Changes in inventories		213	-120
Changes in current receivables		-3,215	-2,213
Changes in current liabilities		5,128	8,053
<b>Net cash from operating activities</b>		<b>-15,367</b>	<b>-21,560</b>
<b>Cash flows from investing activities</b>			
Acquisitions of intangible assets, including capitalized development expenditure	11.12	-1,954	-2,222
Acquisitions of property, plant and equipment	13	-354	-314
Acquisitions/disposals of financial assets		-	-
Acquisitions of subsidiaries	9	- 13,373	-24,891
<b>Net cash from investing activities</b>		<b>-15,681</b>	<b>-27,427</b>
<b>Cash flows from financing activities</b>			
New share issue		-	30,008
Transaction expenses attributable to non-cash and new share issues		-42	-2,307
Option premium		-	8
Option repurchase		-	-352
<b>Net cash from financing activities</b>		<b>-42</b>	<b>27,357</b>
<b>NET CASH FLOW FOR THE YEAR</b>		<b>-31,090</b>	<b>-21,630</b>
Cash and cash equivalents at start of period		67,332	88,962
Cash and cash equivalents at end of period		36,242	67,332
Supplementary cash flow statement disclosures			
Interest received during the year		183	75
Interest paid during the year		-	-

## 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
<b>Opening balance AT 1/1/2018</b>	<b>773</b>	<b>5,908</b>	<b>80,869</b>	<b>0</b>	<b>0</b>	<b>14,068</b>	<b>101,620</b>
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
<b>Closing balance at 31/12/2018</b>	<b>779</b>	<b>7,649</b>	<b>2,445</b>	<b>0</b>	<b>0</b>	<b>75,672</b>	<b>86,546</b>
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
<b>Closing balance at 31/12/2019</b>	<b>1,068</b>	<b>7,341</b>	<b>98,372</b>	<b>0</b>	<b>0</b>	<b>27,956</b>	<b>134,738</b>
2020 loss						-27,257	-27,257
AGM resolution			-98,372			98,372	0
Options			698				698
Development expenditure		-2,218				2,218	0
<b>Closing balance at 31/12/2020</b>	<b>1,068</b>	<b>5,123</b>	<b>698</b>	<b>0</b>	<b>0</b>	<b>101,289</b>	<b>108,179</b>
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
<b>Closing balance at 31/12/2021</b>	<b>1,203</b>	<b>3,037</b>	<b>33,348</b>	<b>0</b>	<b>0</b>	<b>72,924</b>	<b>110,513</b>
2022 loss						-21,357	-21,357
AGM resolution			-33,348			33,348	0
Non-cash issue	6		1,623				1,629
Issue expenses			-42				-42
Development expenditure		-2,131				2,131	0
<b>Closing balance at 31/12/2022</b>	<b>1,209</b>	<b>906</b>	<b>1,581</b>	<b>0</b>	<b>0</b>	<b>87,047</b>	<b>90,744</b>

## 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

SenzaGen's business is to provide complete toxicology solutions for assessing the safety of chemicals, which includes testing and advice. Italy-based CRO VitroScreen S.r.l has been a Group company since 2021 and ToxHub has also been a Group company since 2022. The latter is active in toxicological risk assessment and regulatory strategy consulting within the Group.

### NOTE 3

#### Intra-Group purchases and sales

Of the Parent Company's total purchases and sales, SEK 245 (704) thousand is from intra-Group purchases and SEK 883 (60) thousand from intra-Group sales.

### NOTE 4

#### Leases

The Group has the following operating leases

	Group 2022	2021	Parent Company 2022	2021
Paid during the year	2,667	1,564	1,305	1,398
<b>Future operating leases:</b>				
Maturing within one year	2,720	2,148	1,494	1,327
Maturing within 2-5 years	6,589	6,110	1,681	2,826
Maturing later than 5 years	-	-	-	-
<b>Total future leases</b>	<b>9,309</b>	<b>8,258</b>	<b>3,175</b>	<b>4,153</b>

The lease payments are for cars, machinery and premises.

### NOTE 5

#### Employees and employee benefit expenses

	Group 2022	2021	Parent Company 2022	2021
<b>5.1 Average number of employees</b>				
Men	11	9	8	9
Women	20	12	11	10
<b>Total</b>	<b>31</b>	<b>21</b>	<b>19</b>	<b>19</b>

The number of employees in the Group increased by 3 with the acquisition of ToxHub. These are only counted from 11 November 2022.

<b>5.2 Number of employees at 31 December</b>				
Men	11	12	8	9
Women	24	19	13	11
<b>Total</b>	<b>35</b>	<b>31</b>	<b>21</b>	<b>17</b>

<b>5.3 Expensed salaries and other benefits:</b>				
Salaries and benefits – board and CEO	5,564	4,523	3,692	4,244
Salaries and benefits – other employees	14,446	12,773	11,702	12,099
<b>Total</b>	<b>20,010</b>	<b>17,296</b>	<b>15,394</b>	<b>16,343</b>

## NOTE 5

### Employees and employee benefit expenses, cont'd

	Group 2022	2021	Parent Company 2022	2021
<b>5.4 Social security expenses</b>				
Pension expenses including social security contributions for CEO	398	488	398	434
Pension expenses including social security contributions for other employees	1,794	2,165	1,794	1,911
Other social security contributions	5,513	4,904	4,190	4,862
<b>Total</b>	<b>7,705</b>	<b>7,557</b>	<b>6,382</b>	<b>7,207</b>

	Group 31/12/2022	31/12/2021	Parent Company 31/12/2022	31/12/2021
<b>Gender distribution among senior executives</b>				
Percentage of men on board	50%	50%	50%	50%
Percentage of men among senior executives	33%	25%	38%	29%

## 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	400	-	-	-	400
Laura Chirica, Director	200	-	-	-	200
Anki Malmborg Hager, Director	200	-	-	-	200
Ian Kimber, Director	200	-	-	-	200
Paul Yianni, Director	200	-	-	-	200
Paula Zeilon, Director	200	-	-	-	200
<b>Total for board</b>	<b>1,400</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>1,400</b>
<b>CEO and other senior executives</b>					
Peter Nählstedt, CEO	2,100	175	-	320	2,595
Other senior executives (8 people)	6,835	356	-	945	8,136
<b>Total for senior executives</b>	<b>8,935</b>	<b>531</b>	<b>-</b>	<b>1,265</b>	<b>10,731</b>
<b>Total for board and senior executives</b>	<b>10,335</b>	<b>531</b>	<b>-</b>	<b>1,265</b>	<b>12,131</b>

#### 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 seven employees and one external member.

The 2022 Annual General Meeting (AGM) 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 2022, a total of SEK 147 thousand was paid in remuneration to Ocean Capital.

Director Paul Yianni was hired by SenzaGen on a consulting basis via his company Yianni Consulting. In 2022, a total of SEK 118 thousand was paid in remuneration to Yianni Consulting.

Via his company Kimber Biomedical, Director Ian Kimber has been hired by SenzaGen on a consulting basis to provide scientific and strategic support for the Company. In 2022, a total of SEK 8 thousand was paid in remuneration to Kimber Biomedical.

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 2022.

## NOTE 7

### Fees and remuneration of Company's auditors

	2022 Group	Parent Company	2021 Group	Parent Company
Audit engagement, Mats-Åke Andersson, HLB Auditoriet	434	434	349	349
HLB Analisi, Italy	93	-	-	-
<b>Total</b>	<b>527</b>	<b>434</b>	<b>349</b>	<b>349</b>

At the AGM on 5 May 2022, 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). HLB Analisi in Italy was hired to audit the Italian subsidiaries.

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	
	2022	2021	2022	2021
Interest income	171	75	183	75
Other items	167	112	174	115
<b>Total</b>	<b>338</b>	<b>187</b>	<b>357</b>	<b>190</b>

Interest expenses and similar items	Group		Parent Company	
	2022	2021	2022	2021
Interest expenses	-46	-16	-	-
Other items	-144	-3	-117	-
<b>Total</b>	<b>-190</b>	<b>-19</b>	<b>-117</b>	<b>-</b>

## NOTE 9

### Acquisition analysis

ToxHub s.r.l. acquisition analysis (SEK thousand)		2022
<b>Fair value of acquired assets and assumed liabilities</b>		
Intangible assets, excluding goodwill		3,194
Goodwill		436
Property, plant and equipment		68
Current assets, excluding cash and cash equivalents		1,601
Cash and cash equivalents		2,193
Provisions		-
Non-current liabilities		- 796
Current liabilities		- 1,595
<b>Total fair value of acquired net assets</b>		<b>5,102</b>
Acquisition paid for with:		
Cash		3,473
Non-cash issue of shares in SenzaGen AB		1,629
<b>Total</b>		<b>5,102</b>

## NOTE 10

### Goodwill

	31/12/2022	Group 31/12/2021
<b>Accumulated cost</b>		
Opening cost	13,245	-
Acquisition balance	10,439	13,245
Retirements	-	-
Translation difference	1,167	-
<b>Closing accumulated cost</b>	<b>24,851</b>	<b>13,245</b>
<b>Accumulated amortization</b>		
Opening amortization	-136	-
Depreciation for the year	-2,920	-136
Translation difference	-148	-
<b>Closing accumulated depreciation</b>	<b>-3,204</b>	<b>-136</b>
<b>Closing carrying amount</b>	<b>21,647</b>	<b>13,109</b>

## NOTE 11

### Capitalized development expenditure

	Group		Parent Company	
	31/12/2022	31/12/2021	31/12/2022	31/12/2021
Opening cost	29,046	23,362	23,393	23,362
Acquisition balance	-	5,653	-	-
Acquisitions	-	31	-	31
Translation difference	498	-	-	-
<b>Closing accumulated cost</b>	<b>29,544</b>	<b>29,046</b>	<b>23,393</b>	<b>23,393</b>
<b>Accumulated amortization</b>				
Opening amortization	-5,673	- 3,462	-5,579	- 3,462
Acquisition balance	-	-94	-	-
Depreciation for the year	-3,306	- 2,117	-2,131	-2,117
Translation difference	-64	-	-	-
<b>Closing accumulated depreciation</b>	<b>-9,043</b>	<b>-5,673</b>	<b>-7,710</b>	<b>- 5,579</b>
<b>Accumulated impairment losses</b>				
Opening impairment losses	-12,742	-12,742	-12,742	-12,742
Impairment losses for the year	-	-	-	-
<b>Closing accumulated impairment losses</b>	<b>-12,742</b>	<b>-12,742</b>	<b>-12,742</b>	<b>-12,742</b>
<b>Closing carrying amount</b>	<b>7,759</b>	<b>10,631</b>	<b>2,941</b>	<b>5,072</b>

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 0 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 2022.

## NOTE 12

### Concessions, patents, licenses, trademarks and similar rights

	Group		Parent Company	
	31/12/2022	31/12/2021	31/12/2022	31/12/2021
<b>Accumulated cost</b>				
Opening cost	28,226	9,923	12,114	9,923
Acquisition balance	4,678	15,630	-	-
Acquisitions	1,986	2,673	1,954	2,191
Translation difference	42	-	-	-
<b>Closing accumulated cost</b>	<b>34,932</b>	<b>28,226</b>	<b>14,068</b>	<b>12,114</b>
<b>Accumulated scheduled depreciation</b>				
Opening depreciation	-2,796	-1,714	-2,425	-1,714
Acquisition balance	-13	-65	-	-
Depreciation for the year	-1,715	-1,017	-869	-711
Translation difference	-60	-	-	-
<b>Closing accumulated depreciation</b>	<b>-4,584</b>	<b>-2,796</b>	<b>-3,294</b>	<b>-2,425</b>
<b>Closing carrying amount</b>	<b>30,348</b>	<b>25,430</b>	<b>10,774</b>	<b>9,689</b>

## NOTE 13

### Equipment, tools, fixtures and fittings

	Group		Parent Company	
	31/12/2022	31/12/2021	31/12/2022	31/12/2021
<b>EQUIPMENT</b>				
<b>Accumulated cost</b>				
Opening cost	13,514	5,006	5,306	4,992
Acquisition balance	85	8,177	-	-
Acquisitions	484	331	264	314
Retirement of equipment	-1,291	-	-1,291	-
Translation difference	722	-	-	-
<b>Closing accumulated cost</b>	<b>13,514</b>	<b>13,514</b>	<b>4,279</b>	<b>5,306</b>
<b>Accumulated scheduled depreciation</b>				
Opening depreciation	-10,570	-3,207	-4,041	-3,193
Acquisition balance	-16	-6,427	-	-
Retirement of equipment	1,291	-	1,291	-
Depreciation for the year	-1,322	-936	-779	-848
Translation difference	-599	-	-	-
<b>Closing accumulated depreciation</b>	<b>-11,216</b>	<b>-10,570</b>	<b>-3,529</b>	<b>-4,041</b>
<b>Closing carrying amount</b>	<b>2,298</b>	<b>2,944</b>	<b>750</b>	<b>1,265</b>
<b>FIXTURES AND FITTINGS</b>				
<b>Accumulated cost</b>				
Opening cost	1,958	963	963	963
Acquisition balance	-	995	-	-
Acquisitions	135	-	90	-
Retirement of fixtures and fittings	-600	-	-600	-
Translation difference	88	-	-	-
<b>Closing accumulated cost</b>	<b>1,581</b>	<b>1,958</b>	<b>453</b>	<b>963</b>
<b>Accumulated scheduled depreciation</b>				
Opening depreciation	-1,672	-665	-858	-665
Acquisition balance	-	-799	-	-
Retirement of fixtures and fittings	600	-	600	-
Depreciation for the year	-157	-208	-84	-193
Translation difference	-75	-	-	-
<b>Closing accumulated depreciation</b>	<b>-1,304</b>	<b>-1,672</b>	<b>-342</b>	<b>-858</b>
<b>Closing carrying amount</b>	<b>277</b>	<b>286</b>	<b>111</b>	<b>105</b>
<b>Total closing carrying amount</b>	<b>2,575</b>	<b>3,230</b>	<b>861</b>	<b>1,370</b>

## NOTE 14

### Investments in Group companies

Parent Company	2022	2021
<b>Accumulated cost</b>		
Opening cost	31,101	84
Acquisitions	15,002	31,017
<b>Closing accumulated cost</b>	<b>46,103</b>	<b>31,101</b>
<b>Accumulated impairment losses</b>		
Opening impairment losses	-	-
Impairment losses for the year	-	-
<b>Closing accumulated impairment losses</b>	<b>0</b>	<b>0</b>
<b>Closing carrying amount</b>	<b>46,103</b>	<b>31,101</b>

Name	Headquarters	Company reg. no.	Ownership	Number of shares	Carrying amount
<b>SenzaGen Inc.</b>	North Carolina	C3870650	100%	1,000 shares	84
<b>VitroScreen S.r.l.</b>	Milan, Italy	1345404158	100%	15,000 quotas	40,917
<b>ToxHub S.r.l.</b>	Rome, Italy	15737021004	100%	10,000 quotas	5,102

## 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	24,064,916	0.05	1,203,246
Number/quotient value of shares at end of year	24,188,325	0.05	1,209,416

	2022	2021
<b>Earnings per share</b>		
Earnings per share (SEK)	-1.03	-1.35
Fully diluted earnings per share (SEK)	-1.03	-1.35

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.

	2022	2021
<b>Number of outstanding shares (thousands)</b>		
Weighted average during the year	24,085	23,162
At the end of the year,	24,188	24,065

NOTE 16  
Pledged assets and contingent liabilities

	2022	2021
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	
	31/12/2022	31/12/2021	31/12/2022	31/12/2021
Prepaid rent	570	384	363	322
Prepaid insurance	162	4	162	4
Earned but not invoiced revenue	2,752	222	2,752	222
Other items	903	813	903	813
Total	4,387	1,423	4,180	1,361

NOTE 18  
Accrued expenses and deferred income

	Group		Parent Company	
	31/12/2022	31/12/2021	31/12/2022	31/12/2021
Accrued employee benefit expenses	2,604	3,298	2,399	3,139
Additional consideration – acquisition	10,015	5,113	10,015	5,113
Other items	769	634	766	629
Total	13,388	9,045	13,180	8,881

NOTE 19  
Equity

At 31 December 2022, the share capital comprised 24,188,325 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

2020/2024 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 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.

2022/2025 stock option plan

The AGM on 5 May 2022 resolved to approve the board's proposal to issue a maximum of 812,500 stock options, as a result of which the Company's share capital may increase by a maximum of SEK 40,625.

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

The Group CEO will be offered to subscribe for a maximum of 75,000 options. Members of Group Management and key personnel comprising up to ten positions will each be offered to subscribe for between 25,000 and 50,000 options, altogether comprising a maximum of 450,000 options.

Other employees and consultants considered key personnel in the Group, comprising twenty-one individuals, will be offered to subscribe for between 12,500 and 25,000 options each, altogether comprising a maximum of 287,500 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 2022 to 4 May 2022. 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 barrier conditions have been met, during the period from 1 June 2025 to 30 September 2025 or the earlier date set out in the option rules.

The maximum dilutive effect of the 2022/2025 series is estimated to be no more than 3.27% 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 29 March 2023.

My auditor's report was submitted on 29 March 2023.

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
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
2022	Non-cash issue	6	123,409	1,209,416	24,188,325	0.05

Shareholders <sup>1</sup>	Number of shares	Percentage of share capital and votes
Carl Borrebaeck	1,690,000	7.0
Malin Lindstedt	1,614,845	6.7
Ålandsbanken in place of owner	1,247,505	5.2
Suad Nimani	984,540	4.1
Nordnet Pensionsförsäkring AB	844,926	3.5
Hans Westberg	818,818	3.4
Futur Pension	737,033	3.0
Jonas Pålsson	700,000	2.9
Försäkringsbolaget Avanza Pension	699,680	2.9
Jarl Ingvar Andersson	675,000	2.8
<b>Total for 10 largest shareholders</b>	<b>10,012,347</b>	<b>41.4</b>
Other shareholders	14,175,978	58.6
<b>Total</b>	<b>24,188,325</b>	<b>100.0</b>

<sup>1</sup>The total number of shareholders at 30/12/2022 was 3,047 (3,196) (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 2022 financial year. The Company’s annual report and consolidated financial statements are presented on pages 30–53 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 2022, 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 2022 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 suitability 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 2022 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,  
29 March 2023

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 3,100 shareholders. In addition to the Parent Company, the Group comprises the following wholly-owned subsidiaries: SenzaGen Inc (USA), VitroScreen s.r.l. (Italy) and ToxHub 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 53.

Eight shareholders representing 16% of the total shares and votes in the Company attended SenzaGen's AGM on 5 May 2022 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 2023 AGM comprises Malin Lindstedt, Nomination Committee Chair, Hans Westberg, Jonas Pålsson and the Company's board chairman Carl Borrebaeck. The Nomination Committee had one meeting in 2022 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 2022 AGM re-elected Carl Borrebaeck, Ian Kimber, Peter Nählstedt, Laura Chirica, Ann-Christin Malmborg Hager, Paul Yianni and 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 58.

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 2022. 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 six were extraordinary meetings. The extraordinary board meetings involved approval of the issue of stock options and the acquisition of ToxHub. At all regular board meetings, the CEO informed directors of the Group's financial position and of significant events in the Company's business. 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 2022 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 2022 AGM for a term lasting until 2023.

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 2022. 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 60.

Remuneration of the CEO and other senior executives

The 2022 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	15 of 15
Laura Chirica	14 of 15
Ann-Christin Malmborg Hager	15 of 15
Paula Zeilon	15 of 15
Paul Yianni	14 of 15

# 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 Biolnvent 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:**  
CEO of Cellevate AB. 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 Malmberg 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, Colzyx AB and NanoEcho 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:**  
30,000 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 Board director at Bio-works AB.

#### Shareholding:

27,119 shares and 100,000 stock options.

Shareholdings at 11 March 2022



### 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 100,000 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:

None.

#### Shareholding:

19,153 shares and 100,000 stock options.



### 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, Cella-Vision and Enzymatica.

#### Other significant appointments:

Board director at Medimi AB.

#### Shareholding:

1,000 shares and 100,000 stock options.



### ANDY FÖRRERYD

VP Sales.  
Employed 2017. Member of the management team since 2022. Born 1984.

#### Education:

MSc. in Biotechnology Engineering, PhD in Immunotechnology.

Andy Forreryd has many years' experiences working with *in vitro* assay development, genomics and machine learning. He is a specialist in biomarker discovery, a skilled research communicator and a co-developer of the GARD technology platform

#### Other significant appointments:

None.

#### Shareholding:

500 shares and 30 000 warrants.



### 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 20,000 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 and 25 000 warrants.



### 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 100,000 stock options.



### 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 and 50 000 warrants.

FINANCIAL SUMMARY

	2022	2021	2020	2019	2018
Net sales, SEK thousand	41,770	15,422	7,958	2,724	1,997
Capitalized developed expenditure, SEK thousand	-	31	334	1,110	1,741
Profit/loss for the year	-24,912	-31,346	-27,168	-50,237	-16,090
Equity ratio, %	75	82	97	94	95
Quick ratio, %	179	332	2,477	2,173	1,307
Equity, SEK thousand	89,701	110,243	107,792	134,211	85,936
Average number of employees	31	21	18	22	17
Number of employees at year-end, converted to full-time equivalents	35	31	17	23	19
Average number of shares	24,085,484	21,808,849	21,357,636	16,175,772	15,525,563
Number of shares at end of period	24,188,325	24,064,916	21,357,636	21,357,636	15,578,000
Earnings per share, SEK¹	-1.03	-1.35	-1.27	-3.11	-1.04
Fully diluted earnings per share, SEK²	-1.03	-1.35	-1.27	-3.11	-1 ,04
Equity per share, SEK	3.71	4.58	5.05	6.28	5.52
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

4 May 2023 Annual General Meeting  
24 August 2023 January-June 2023 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.

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.

QSAR

Quantitative structure-activity relationships – a computer-aided model for drug discovery.

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.

Read-across

Expert assessments based on existing data for similar chemicals.

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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3 National Center for Biotechnology Information 2010 – ncbi.nlm.nih.gov/pubmed/20053163.  
4 Alternatives to Animal Experimentation 2018 –ncbi.nlm.nih.gov/pub-med/30008008.  
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6 Swedish Medical Products Agency, Förbud mot djurförsök.  
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9 International Organization for Standardization.  
10 Swedish Board of Agriculture.  
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12 Clinical Trials – clinicaltrials.gov.  
13 Validation study, OECD Test Guideline Program (TGP no. 4.106). Johansson H. et al. Toxicological Sciences 2019.  
14 Journal of Allergy, 2011 – ncbi.nlm.nih.gov/pmc/articles/PMC3124934/.  
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# SENZA GEN

SenzaGen aims to be an *in vitro* testing leader, driving the transition from animal testing to methods better suited to reflect human biological reactions to toxic substances. The Company provides human-relevant, high-performance, non-animal test methods and innovation and advisory services based on state-of-the-art technology.

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