# 5 ENZA GEN 2023

ANNUAL REPORT SENZAGEN AB (PUBL)



## Contents

#### **TO OUR SHAREHOLDERS**

About SenzaGen	.3
The year at a glance	. 5
The year in numbers	. 6
Message from the CEO	. 7

#### **BUSINESS DESCRIPTION**

Growth strategy	9
Trends and drivers	
Market size and potential	14
How industry uses GARD	16
SenzaGen's offering	17
Innovations based on the latest technology	22
Sustainability report	23

#### SenzaGen AB

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SenzaGen AB is headquartered in Lund and listed on Nasdaq First North. (Ticker symbol: SENZA).

#### FINANCIAL INFORMATION

Directors' report	
Consolidated income statement	
Consolidated balance sheet	
Consolidated cash flow statement	
Consolidated statement of changes in equity	
Parent Company income statement	35
Parent Company balance sheet	
Parent Company cash flow statement	
Parent Company Statement of changes in equity	
Notes	41
Share capital changes	
Auditor's report	52
CORPORATE GOVERNANCE	
Corporate governance report	
Board of Directors	
Management	57
FURTHER INFORMATION	
Financial summary	
Definitions	
Financial calendar	
Glossary, sources	60

## About SenzaGen

#### **Business concept and vision**

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 biology.

We provide high-performance, non-animal test methods and innovation and advisory services based on state-ofthe-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.

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

#### A market with great potential

The *in vitro* toxicology testing market is global and growing strongly. The market is experiencing a paradigm shift as companies around the world transition from animal to non-animal testing. SenzaGen estimates its addressable market at approximately SEK 30 billion. Our market segments are cosmetics, chemicals, medical devices, pharmaceuticals and nutrition/food additives.

#### **Business model**

The majority of the Company's sales are direct sales supplemented by a global network of licensed CROs. Direct sales build strong, long-term customer relationships while the global network of licensed CROs provides flexibility and scalability. SenzaGen's customer base comprises leading multinationals primarily based in Europe and North America.

#### **Growth strategy**

We have a growth strategy centered around continued commercialization of our proprietary test platforms GARD<sup>®</sup> and VitroScreen ORA<sup>®</sup>, expansion of our test portfolio and acquisitions of profitable and growing companies with complementary offerings.

#### 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 while decreasing the number of animal tests.

#### Market segments



Cosmetics



Chemicals



Medical devices



**Pharmaceuticals** 



Nutrition/ food additives

## Our non-animal offering

With broad expertise in various domains of technology, including genomics, machine learning and human tissue models, we offer complete non-animal solutions for assessing the safety of chemicals. Our offering includes testing, advisory and innovation services.

PART OF THE VALUE CHAIN	OFFERING	<b>GROUP COMPANIES</b>
<b>Testing strategy</b> Advice and strategies for toxicology safety assessments	Consulting on how to combine tests	TOX HUB VitroScreen
<i>In silico</i> Computer-simulated assessment of toxic- ity in drug candidates, chemicals, medical devices and food additives	Studies and consulting: QSAR and read-across with expert assessment of results	тох НИВ
<i>In vitro</i> testing Cell-based identification of toxic properties in drug candidates, chemicals, cosmetics and medical devices.	<ul> <li>Innovative patented tests: GARD<sup>®</sup> and ORA<sup>®</sup></li> <li>GLP Regulatory toxicology testing</li> <li>Pre-clinical testing</li> <li>Innovation services</li> </ul>	SENZA GEN - VitroScreen
<b>Regulatory documentation and support</b> Toxicological and pharmacological assess- ment of results and compilation of regula- tory information.	Independent advice for regulatory compliance.	тох НИВ

## The year at a glance

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SenzaGen won an order for GARD<sup>®</sup>skin worth about SEK 1 million from a new chemicals customer. A report from the European Chemicals Agency (ECHA) showed that the use of *in vitro* methods for chemical risk assessment is on the rise. SenzaGen's collaboration with RIFM in fragrance safety and non-animal photosensitization continued to grow with a new project worth SEK 1.6 million.

**Q**3

SenzaGen broadened its market presence with expanded distribution channels in France and India. A new global biotech industry leader ordered skin sensitization tests including GARD®skin, valued at SEK 1.7 million.

Q4

A strategically important order for GARD<sup>®</sup>skin was secured from a new customer, a world leader in fast-moving consumer goods (FMCG).

Deloitte ranked SenzaGen one of Sweden's fastest-growing technology companies according to its annual ranking, Sweden Technology Fast 50.



isted as One of Sweden's Fastest rowing Technology Companies in the eloitte Sweden Technology Fast 50 - 20

Q1

## The year in numbers

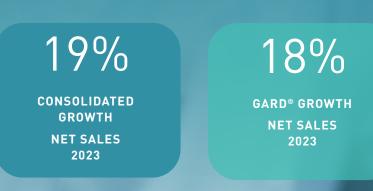
#### FINANCIAL SUMMARY

SEK million	2023	2022	2021	2020	2019
Net sales	49.9	41.8	15.4	8.0	2.7
Gross margin %	70	65	61	70	47
EBITDA	-10.9	-15.7	-27.3	-22.7	-34.7
Cash and cash equiv- alents	17.6	40.0	69.1	89.3	120.5

#### FINANCIAL PERFORMANCE



Total sales increased by 19% during the year, reaching nearly SEK 50 million, driven by strong demand for both our core platform, GARD<sup>®</sup>, and VitroScreen's pre-clinical efficacy tests.



## Continuing strong growth and addition of new major customers taking us to breakeven

We are very proud to look back on yet another successful year, in which we clearly established our tests in the market. Our sales have grown significantly in recent years and 2023 was no exception. Sales increased to SEK 50 million and we were named one of Sweden's fastest growing technology companies. Emboldened by our successes, we are vigorously continuing our growth journey and are poised to soon reach breakeven and become a leader in non-animal testing.

#### Strategies for continuing growth

The SenzaGen Group has established a strong market position with a unique non-animal skin sensitization test and a growing test and service portfolio in non-animal toxicology and pre-clinical efficacy testing. Our concept replaces animal testing and provides significantly better efficacy and accuracy for humans.

We are continuing to pursue our overall growth strategy based on organic growth leveraging both direct and partner sales and on product development. We have taken key steps in executing our strategy during the year. For instance, we increased our marketing activity in Europe and the US, added two new distribution partners, and continued our innovative development activities.

We are also positioning the Company as a thought leader in non-animal testing via scientific work and communications in collaboration with world-leading companies such as L'Oreal, Exxon Mobil and Sonova. In addition, we have an acquisition agenda that further accelerated growth. Being ranked a fast grower demonstrates that our business model has delivered outstanding results and that we are doing is truly in tune with the times.

#### Growing customer base in several broad indus-

**tries** Our GARD® business exhibited impressively strong performance during the year with several of the top companies in the world as customers. Customers have a high repeat purchase rate and we see about twice as high order values up to half a million SEK after the first order. Going from 18 new customers in 2022 to as many as 32 new customers in 2023 opens up great opportunities to further build our business towards profitability. Our direct sales activities primarily target major global cosmetics, chemicals and medical devices companies.

During the year, both of our Italian subsidiaries stepped up their marketing activities in the cosmetics and pharmaceuticals industries, and the results were excellent. Especially in the latter part of the year, VitroScreen saw strong growth in demand driven by pre-clinical efficacy tests and growing sales of VitroScreen ORA®. As a result, the fourth quarter was VitroScreen's best quarter ever. ToxHub has been smoothly integrated into our corporate group and their consulting is included in an increasing number of quotes with positive results already observed early on in the year.

In the second half of the year we reduced our operating expenses at the same time as sales increased significantly, which has us now brought us very close to breakeven.

#### Increased efficiency and improved margins

While growth is a priority, effective cost controls are equally important. Our work on pricing and increased efficiency in our testing operations have resulted in an improved gross margin for both GARD<sup>®</sup> and Vitro-Screen tests, which increased from 65% to 70%. We are cost-conscious in everything we do, and in the second half of the year we reduced our operating expenses at the same time as sales increased significantly, which has us now brought us very close to breakeven.

During the year, we secured a financing solution in the form of an overdraft facility from SEB to continue growing after breaking even. SenzaGen meets the requirements of a sustainable growth company, and as a result, also qualified for funding via the European Investment Fund (EIF), which enabled the very favorable terms we obtained from SEB.

#### Innovation – key to the future

It should go without saying that our innovative development activities play a key role for our future. During the year, our goal in development was to be on the cutting edge in our domains of technology. We are engaged in several projects within the Group to both develop new non-animal tests and obtain regulatory approval for the tests that have already been developed. For instance, we are currently working on adapting GARD<sup>®</sup> to measure photosensitization, a joint project with the prestigious US Research Institute for Fragrance Materials (RIFM). We also made good progress on our efforts to achieve the status of a standard skin sensitization method under ISO 10993-10.

In addition, we will continue to introduce supplementary regulatory tests in our labs in order to offer an even broader test portfolio to our customers, further strengthening our position as an *in vitro* toxicology leader.

### One of Sweden's fastest growing technology companies

Our strong growth was recognized during the year by Deloitte, which named SenzaGen one of Sweden's fastest growing technology companies in Sweden Technology Fast 50. Being ranked a fast grower demonstrates that our business model has delivered outstanding results and that we are doing is truly in tune with the times. Our annual growth has increased by an average of 100% in the last five years.

I am incredibly proud to have the pleasure of leading this team that has delivered such great results in such a short time with new technology in an industry in transition, and I would like to express my deepest gratitude to all of our dedicated employees and to our shareholders, who are an integral part of our success story.

As president and CEO, I feel greatly energized and motivated to tackle 2024 together with our outstanding employees. There is no doubt whatsoever that non-animal tests are the future of chemical and product safety testing, and we are creating a very exciting future with one of Sweden's fastest growing technology companies.

#### Lund, March 2024

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.

#### Modern high-tech lab

SenzaGen 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<sup>®</sup> platform.

VitroScreen 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.

#### **ORGANIC GROWTH**

#### Direct sales

Sales via in-house sales forces in Sweden and Italy. Broaden customer base of large multinationals with recurring testing needs.

#### Partner sales

Global network of licensees and distributors provide flexibility and scalability.

#### Broaden test portfolio

Innovation pipeline with more endpoints, regulatory status and implementation of supplementary regulatory ry tests.

#### Thought leadership

Positioning the Company as a thought leader in non-animal testing via scientific work and communications.

#### **ACQUISITION-DRIVEN GROWTH**

Focus on profitable and growing companies with complementary offerings.

Value chain

Increased presence in more parts of the value chain.

**Endpoints** Supplementary *in vitro* tests for mor<u>e endpoints.</u>

#### ORGANIC GROWTH 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. Sales work is performed by in-house sales forces in Sweden and Italy. The Company is focused on broadening its customer base of large, multinationals with recurring testing needs. On behalf of customers, the labs perform tests to evaluate the toxicological properties or preclinical efficacy of various substances.

Working with large customers also leads to further insights on testing needs and provides more knowledge about the capacities and possibilities for expanding the GARD<sup>®</sup> and VitroScreen ORA<sup>®</sup> platforms as well as how to develop new sustainable tests.

To scale up GARD<sup>®</sup> sales, the Company also works with a global network of distributors comprising CROs with *in vitro* toxicology expertise and a network of customers in various industries. SenzaGen also has agreements with CROs in Europe and the US that perform GARD<sup>®</sup> under license, including Eurofins in Germany, which provides flexible testing capacity.

#### **Thought leadership**

The Company's sales and marketing activities also include scientific communication initiatives to build thought leadership by promoting dialogue and knowledge sharing within the toxicology industry and among researchers. SenzaGen proactively stimulates scientific discussion by publishing scientific posters, webinars and articles in collaboration with customers and thought leaders. This boosts the Company's credibility, attracts customers and positions the Company as a leader in non-animal testing.

#### **Obtain regulatory status**

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 *in vitro* tests. Regulatory approval broadens the area of usage and enables customers to use test results not only in the product development phase but also for product filings.

#### **Broaden in vitro offering**

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 expansion of the Company's test offering includes the development of new innovative tests for more endpoints. For instance, we are working on adapting GARD<sup>®</sup> skin to measure photosensitization. SenzaGen and VitroScreen have vast expertise in genomics, machine learning and 3D human tissue models.

Tests for supplementary endpoints are currently being implemented for the regulatory test portfolio for toxicology.

#### 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 companies that are profitable and growing with complementary offerings, in terms of increased value chain presence, tests for more endpoints, 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.

## Test order cycle

GARD<sup>®</sup> customers have a high repeat purchase rate and customers tend to have greater testing needs in year 2 than year 1. Implementing GARD<sup>®</sup> in large multinationals builds a growing sales cycle.



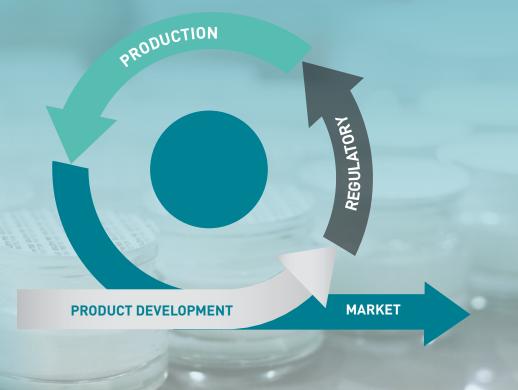
As many as 32 new  ${\rm GARD}^{\otimes}$  customers were gained in 2023, compared with 18 in the previous year.





Our services are needed when our customers introduce a new product in the market or reformulate an existing product.

The development process for a product containing chemicals includes several steps in which SenzaGen's services play a crucial role. Most of the testing takes place in the product development phase, which is when new product candidates are assessed to determine if they meet regulatory safety requirements.



## 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. 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.

#### **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>

## 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 was 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>

#### **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 2024.

#### 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.

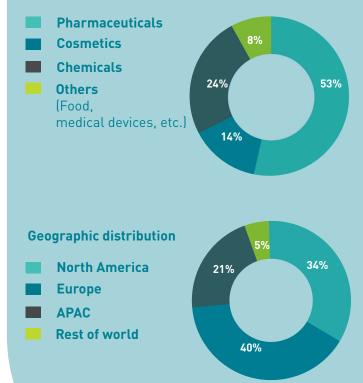
#### **Respiratory sensitization**

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.

#### Cytotoxicity

Cytotoxicity (toxicity to cells) testing is a part of the biological evaluation that all medical devices must undergo before being brought to market. SenzaGen has offered these tests to medical device customers since 2022, which has opened up new opportunities for the Company. In vitro toxicology market<sup>11</sup>

#### Industry segment distribution



\* Data confirmed by In Vitro Toxicology Testing Market Global Forecast to 2028, MarketsandMarkets 2023.

#### 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 oft he 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 increasing and significant from the pharmaceuticals and cosmetics industries.

#### 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 test methods that are an alternative to animal testing. 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.

ToxHub, which offers consulting services for regulatory strategies and non-animal tests, gives the Group the capability to more effectively help customers with regulator contacts and selection of test methods.

#### **REGULATORY REQUIREMENTS**

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

#### 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

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## How industry uses GARD®

### EXXONMOBIL

- 18

In a new study, oil and gas company ExxonMobil assessed how well GARD<sup>®</sup>skin works for chemicals that are usually difficult to assess using traditional test methods, such as complex mixtures and UVCBs. The results from the study provided valuable insights into chemicals with challenging properties and underlined the usability of the test for a weight-of-evidence submission.

Assessing the Utility of the Genomic Allergen Rapid Detection (GARDskin) Assay to Detect Dermal Sensitization Potential in UVCBs and Formulated Lubricant Products

T. Lindberg<sup>2</sup>, A.Greminger<sup>1</sup>, K. Goyak<sup>1</sup>, O. Larne<sup>2</sup>, R. Gradin<sup>2</sup>, and A. Forreryd<sup>2</sup> I <sup>1</sup> ExxonMobil Biomedical Sciences Inc., Annandale, NJ; and <sup>2</sup> SenzaGen AB, Lund, Sweden



SONOVA

The benefits of using GARD® early in the development of medical device products are seen clearly in Sonova, a leading supplier of hearing solutions. New scientific data demonstrates that the test can discover sensitizing substances in complex extracts from solid materials with higher sensitivity than animal tests. This reduces the need for animal testing and improves product safety while also helping companies prevent costly mistakes later in the development cycle.

Unveiling skin sensitizing potential: case studies on biocompatible material development utilizing the in vitro GARD®skin Medical Device assay A. Forreryd<sup>1</sup>, D. Waeckerlin<sup>2</sup>, K. Lienau<sup>2</sup>, M. Burkard<sup>2</sup>, R. Gradin<sup>1</sup>, H. Johansson<sup>1</sup> I <sup>1</sup> SenzaGen, Lund, Sweden, and <sup>2</sup> Sonova AG, Staefa, Switzerland L'ORÉAL



During the year, L'Oréal assessed GARDskin Dose-Response as an alternative method to animal testing in order to identify a point of departure for risk analysis of cosmetic products. The study confirmed that the test is usable for predicting the sensitizing potency of chemicals, enabling toxicologists to identify safe doses of individual ingredients in cosmetic products without having to resort to animal testing.

Improved Confidence of Quantitative Sensitizing Potency Assessment for Point of Departure Using GARDskin Dose-Response

F. Amaral<sup>1</sup>, A. Forreryd<sup>2</sup>, R. Gradin<sup>2</sup>, F. Tourneix<sup>1</sup>, U. Mattson<sup>2</sup>, J. Andersson<sup>2</sup>, N. Alépée<sup>1</sup>, H Johansson<sup>2</sup>. I <sup>1</sup> L'Oreal Advanced Research, Aulnay sous Bois, France; and <sup>2</sup> SenzaGen AB, Lund, Sweden

SENZAGEN GROUP OFFERING

## Innovative solutions replace animal tests with leading *in vitro* technology

With its broad and collective expertise and a growing test portfolio, 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.

## Toxicology safety testing

## The GARD<sup>®</sup> 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.

#### **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 annex to the most recent ISO standard 10993-10.

#### GARD®skin Dose-Response

GARD<sup>®</sup>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<sup>®</sup>skin, providing quantitative information, and is one of the first of its kind on the market. The test is in the process of OECD validation.

## SENZAGEN



#### **UNIQUE GARD® BENEFITS**

High performance with over 90% accuracy depending on application area

**Broad applicability** also effective for difficult-to-assess chemicals

#### **Cost benefits** small sample volumes per test enable competitive pricing

#### **GARD®potency**

GARD<sup>®</sup>potency was the first non-animal test method to provide 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<sup>®</sup>skin and provides qualitative information about the substances assessed as allergenic. The test has been further developed into GARDskin Dose-Response, which 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. Evalating whether chemicals can impact the respiratory system is also important in biotech and drug manufacturing.

#### Regulatory toxicology test portfolio

Supplementary endpoints.

Endpoint	Test
Skin sensitization, GARD®skin	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

**SenzaGen** is an innovative company that has developed GARD<sup>®</sup>, 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 expertise in skin toxicology, genomics and machine learning. SenzaGen became an operating company in 2014 and has 21 employees.

## Toxicology 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 and 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. Via 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.

#### **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 can provide advice on *in silico* studies and we can also perform them via partners.



**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.

### Pre-clinical efficacy testing

#### Penetration, absorption and distribution

Via VitroScreen, the SenzaGen 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 3D tissue models developed by VitroScreen, which are available for several indication areas: the skin, legs, eyes, respiratory tracts, gynecology, urology, the abdomen and the liver.

#### 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.

## The VitroScreen ORA<sup>®</sup> platform for organ toxicity and efficacy

VitroScreen's proprietary organoid model VitroScreen 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 SenzaGen Group commands expertise spanning the entire organoid platform testing chain with development, production, testing and consultation. The VitroScreen 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.

> 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 preclinical testing, advisory services, and human 3D tissue 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,

-VitroScreen

## Innovations based on the latest technology

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.

#### GARD<sup>®</sup> – improved accuracy and human relevance

The GARD<sup>®</sup> 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<sup>®</sup> improved accuracy and clinical relevance.

Traditional *in vitro* tests investigate only a few biomarkers, providing limited information and less 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<sup>®</sup> 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 VitroScreen 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 VitroScreen 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*.

#### 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 its patented technology platforms, GARD<sup>®</sup> and VitroScreen ORA<sup>®</sup>, and based on VitroScreen's experience in 3D models, microbiota and histomorphology. The innovation units solve customer-specific challenges in various domains of the pharmaceuticals, cosmetics, nutrition and chemicals industries.

For instance, in 2022, the Group pooled its expertise in 3D cell models and data analysis based on its 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.



#### Scientific articles and patent protection

- 26 published articles.
- 6 patent families for GARD<sup>®</sup> and VitroScreen ORA<sup>®</sup>.
- 2023: Patent granted in the US for SenzaCell<sup>™</sup>, which protects the biological cell system used in all GARD<sup>®</sup>-tests.

## Sustainability report

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

#### 2023 progress

In 2023, SenzaGen's headquarters worked on strengthening the connection between employee engagement and the Company's goals. Based on the results of the situation analysis, the Company also started measuring customer satisfaction and conducted work environment surveys as a part of its systematic work environment efforts. With the initiatives taken during the year, the Company has strengthened its commitment to lay the foundation for sustainable growth.

#### **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.

#### **Highly satisfied customers**

Satisfied customers are decisive for repeat purchases and willingness to recommend us to other companies. SenzaGen in Lund performed very well in the customer satisfaction survey conducted in 2023. On a scale from 1 to 10, we scored 9.41 on customer willingness to recommend us to others, corresponding to a Net Promoter Score (NPS) of 81. We are motivated by very high points in areas such as employee knowledge and expertise along with our ability to meet customer expectations.

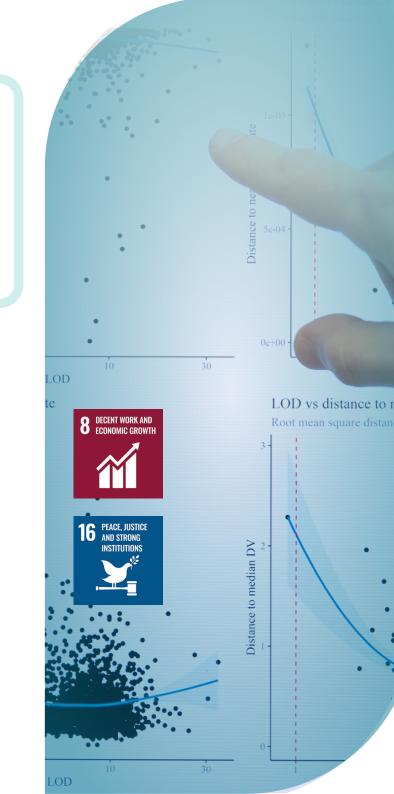
#### Quality management system

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, including customer focus, continual improvement and engagement of people. The policy reflects SenzaGen's views on quality, and all employees must follow and integrate the policy into their daily work.

VitroScreen's laboratory in Milan is certified to 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 national regulators: Swedac in Sweden and the Ministry of Health in Italy.

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.

The Company's headquarters at Medicon Village in Lund, Sweden is connected to the science park's technical energy solution, ectogrid<sup>™</sup>. 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.





25

#### 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)
- 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 benefit from 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 motivation are essential to good performance, efficiency and high-quality work. Combined with efficient processes and tools, this helps the Company grow.

#### Skills, motivation and attitudes

Recruiting and retaining dedicated and qualified employees is essential to realizing the Company's business strategies. The right experience, motivation 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 a high level of business know-how and specialized expertise.

#### Culture and values

To succeed in its mission, SenzaGen strives to create a culture where everyone individually takes responsibility for their tasks and collaborates efficiently on projects and solving problems. An open and transparent corporate culture builds trust and enables development, which in turn increases motivation and efficiency within the organization.

#### Health, safety and equality

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 issues including the work environment, gender equality, and harassment and discrimination.

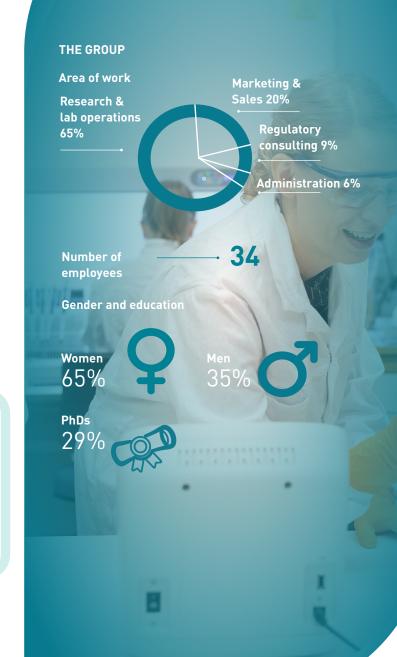
To promote a sound work environment and health, SenzaGen offers its employees in Lund a wellness allowance and encourages health initiatives. Employees are encouraged to maintain a good work-life balance to avoid stress and illness. Questions of well-being, job satisfaction and perceived health situation are taken up during the Company's annual performance reviews.

The rate of absence due to illness at SenzaGen's headquarters is continuously analyzed to discover changes.

At the end of the year, the number of Group employees was 34 (35), 22 were women (24) and 12 were men (11).

#### Proud employees

Employee surveys and performance reviews lay the foundation for how SenzaGen works to develop its organization and keep employees motivated and engaged. In the 2023 employee survey, the statement "I am proud to work at SenzaGen" scored 9.28 on a scale from 1 to 10, a high score and a strong showing for SenzaGen as an employer.



### 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 2023 financial year.

#### **Business**

The SenzaGen Group aims to be an *in vitro* testing leader, driving the transition from animal testing to methods better suited to reflect human biology. The Group provides high-performance, non-animal test methods and innovation and advisory services based on state-of-the-art 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. SenzaGen's growth strategy is centered around continued commercialization of its proprietary GARD<sup>®</sup> and VitroSceen ORA<sup>®</sup> test platforms, expansion of its test portfolio and acquisitions 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 34 (35) at year-end. 22 (24) of the employees were women and 12 (11) were men. More information is provided under the Section about employees in the sustainability report on page 30-31.

#### Research and development

SenzaGen invests in research and development to advance new high-tech and human-relevant *in vitro* methods for effective safety assessment. 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 VitroScreen ORA®, the Group can also provide customers with tailored solutions for a specific test method, cell or organ type. In 2023, the company continued to invest in the GARD<sup>®</sup> platform's IP protection in several countries in Europe, North America and Asia. A patent was granted in the US for SenzaCell<sup>™</sup>, which protects the biological cell system used in all GARD<sup>®</sup>-tests.

#### Financial performance

Consolidated net sales for full year 2023 totaled SEK 49.9 (41.8) million, a 19% year-on-year increase. GARD® sales accounted for SEK 25.4 (21.5) million, representing an 18% increase. Acquired sales from ToxHub accounted for 7% of total net sales.

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.

Consolidated gross profit was SEK 34.9 (27.3) million, corresponding to a gross margin of 70% (65%). This improvement is attributable to both acquired and existing operations.

Operating expenses for the year totaled SEK 58.1 (53.6) million. The increase in costs is attributable to forward-looking investments in line with the Company's growth strategy, which includes the ToxHub acquisition (Nov 2022).

Operating expenses include depreciation and amortization amounting to SEK 11.6 (9.4) million, and SEK 7.5 (4.9) million of this amount is for depreciation and amortization on acquired assets. Excluding acquisitions, depreciation and amortization, operating expenses increased by SEK 2.8 million or 6.5% year-onyear while revenue increased by 19%.

Consolidated EBITDA amounted to SEK -10.9 (-15.7) million.

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 1.4 (2.0) million, with patents and trademarks accounting for SEK 1.4 (2.0) million of this amount. Capitalized expenditure for in-house development projects totaled SEK 0 (0) thousand.

The Group's cash and cash equivalents at the end of the year totaled SEK 17.6 (40.0) million.

Net cash from operating activities for the year was SEK -16.4 (-16.0) million. Cash flow was impacted by increased trade receivables amounting to SEK 10.6 (9.1) million due to deliveries at the end of the period. Total net cash flow for the year amounted to SEK -22.4 (-29.5) million.

During the year, 720,000 stock options were subscribed by employees under the incentive program adopted by the 2023 AGM.

The 2023 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 2023 AGM.

At the end of the year, SenzaGen secured an overdraft facility in the amount of SEK 7.5 million from SEB. The facility is backed by a guarantee commitment under the European Investment Fund (EIF).

#### Significant events during the year

- 23 FEB. SenzaGen won an order for GARD® skin worth about SEK 1 million from a new chemicals customer.
- 11 MAY. SenzaGen entered into an agreement with Erik Penser Bank AB regarding market making.
- 07 JUL. SenzaGen strengthened its market presence with expanded distribution channels in France and India.
- 28 SEP. SenzaGen continued to collaborate with RIFM in non-animal photosensitization receiving a new grant worth SEK 1.6 million.
- 26 OCT. SenzaGen secured a strategically important order from a new customer, a world leader in fast-moving consumer goods (FMCG).
- 08 NOV. Deloitte ranked SenzaGen one of Sweden's fastestgrowing technology companies (Sweden Technology Fast 50).
- 29 NOV. SenzaGen changed its market maker to Carnegie due to the bank's acquisition of business areas from Erik Penser Bank.
- 18 DEC. SenzaGen received a SEK 1.7 million order from a new customer, a global biotech industry leader.

#### **Risks and uncertainties**

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

#### 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.

#### Suppliers

SenzaGen works with several suppliers. It cannot be ruled out that one or more of these suppliers may choose to stop working with the Company, which could have a negative impact on the Company's operations. The Company is dependent on its suppliers meeting agreed requirements in terms of quantity, quality and delivery time. Incorrect or missed deliveries from suppliers could lead to delayed deliveries to customers, resulting in lost sales.

#### Distributors and license partners

Partner sales currently account for a small share of SenzaGen's total revenue but play an important role in the long term for the Company's marketing and sales activities. Agreements with distributors make it easier to scale up sales, and license agreements provides flexible testing capacity. There is no guarantee that the partners with which the Company has signed partnership agreements will be able to fulfil their obligations, and it cannot be ruled out that disruptions to partners or termination of partnerships could lead to delayed or lost revenue.

#### Customers

SenzaGen has direct sales targeting primarily large companies with global operations. The customers operate within stable industries, and orders can amount to several million kronor. It cannot be ruled out that some of these customers may not pay invoices on time or go bankrupt, which can lead to a negative impact on the company's results.

#### 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	51,913,131
Share premium reserve	37,621,557
Profit/loss for the year	-16,347,755
The board proposes that the following amount be carried forward	-73,186,933

#### Dividend

The board proposes no dividend for the 2023 financial year.

### CONSOLIDATED INCOME STATEMENT

SEK thousand	Note	2023	2022
	1		
Operating income			
Net sales	2	49,870	41,770
Cost of goods sold		-14,938	-14,434
Gross profit/loss		34,932	27,336
Operating expenses	4,5,6,7,8		
Selling expenses		-26,787	-21,609
Administrative expenses		-19,138	-17,418
Research and development expenditure		-3,747	-8,985
Acquisition-related expenses		-7,518	-4,921
Other operating income		689	1,189
Other operating expenses		-917	-703
Operating profit/loss		-22,486	-25,111
Profit/loss from financial items			
Interest income and similar items	8	764	338
Interest expenses and similar items	8	-254	-189
Profit/loss after financial items		-21,976	-24,962
Profit/loss before tax		-21,976	-24,962
		21,770	
Tax on profit/loss for the year		-121	50
PROFIT/LOSS FOR THE YEAR		-22,097	-24,912
Share of profit/loss attributable to Parent Company shareholders		-22,097	-24,912
Share of profit/loss attributable to minority interests		_	_

### CONSOLIDATED BALANCE SHEET

SEK thousand	Note	2023	2022
	1		
ASSETS			
Non-current assets			
Intangible assets			
Goodwill	9	20,993	21,647
Capitalized development expenditure	10	4,389	7,759
Concessions, patents, licenses, trademarks and similar rights	11	29,628	30,348
Total intangible assets		55,010	59,754
Property, plant and equipment			
Equipment, tools, fixtures and fittings	12	1,811	2,575
Total property, plant and equipment		1,811	2,575
Total non-current assets		56,821	62,329
Current assets			
Inventories		6,228	3,614
Total inventories		6,228	3,614
Current receivables			
Trade receivables		10,589	9,094
Other receivables		1,769	554
Earned but not invoiced revenue	16	2,328	2,752
Prepaid expenses and accrued income	16	1,817	1,635
Total current receivables		16,503	14,035
Cash and bank balances		17,624	39,976
Total current assets		40,355	57,625
TOTAL ASSETS		97,176	119,954

### CONSOLIDATED BALANCE SHEET

SEK thousand	Note	2023	2022
	1		
EQUITY AND LIABILITIES			
Equity	18		
Share capital		1,209	1,209
Other contributed capital		55	921
Retained earnings		84,721	108,897
Profit/loss for the year		-22,097	-24,912
Translation differences		3,720	3,586
Total equity attributable to Parent Company shareholders		67,608	89,701
Non-current liabilities			
Liabilities to credit institutions		1,673	1,207
Total non-current liabilities		1,673	1,207
Current liabilities			
Trade payables		5,691	4,420
Other provisions		6,571	7,321
Current tax liabilities		421	411
Other liabilities		2,916	3,506
Invoiced but not earned revenue		367	99
Accrued expenses and deferred income	17	11,929	13,289
Total current liabilities		27,895	29,046
TOTAL EQUITY AND LIABILITIES		97,176	119,954

SEK thousand Note	2023	2022
1		
Cash flows from operating activities		
Profit/loss after tax	-22,097	-24,912
Adjustments for non-cash items		
Depreciation and amortization 9,10,11,12	11,585	9,420
Impairment losses 10	-	-
Foreign currency translation, unrealized	-178	225
Тах	-579	-500
Changes in working capital		
Changes in inventories	-2,623	-158
Changes in current receivables	-2,860	-4,190
Changes in current liabilities	296	4,051
Deferred tax liabilities	3	-7
Net cash from operating activities	-16,453	-16,071
Cash flows from investing activities		
Acquisitions of intangible assets, including capi- talized development expenditure 9,10,11	-3,679	-1,982
Acquisitions of property, plant and equipment 12	-129	-607
Acquisitions/disposals of subsidiaries	-2,295	-13,041
Acquisitions/disposals of financial assets	21	2,193
Net cash from investing activities	-6,082	-13,437
Cash flows from financing activities		
Transaction expenses attributable to new share issue	-	-42
Change in non-current liabilities to credit institu- tions	147	73
Net cash from financing activities	147	31

SEK thousand	Note	2023	2022
NET CASH FLOW FOR THE YEAR		-22,388	-29,477
Cash and cash equivalents at start of period		39,976	69,164
Translation difference on cash and cash equiva- lents		36	289
Cash and cash equivalents at end of period		17,624	39,976
Supplementary cash flow statement disclosures			
Interest received during the year		564	171
Interest paid during the year		-37	-28

### CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

SEK thousand	SHARE CAPITAL	OTHER CONTRIBUTED CAPITAL	ACCUMULATED LOSS	TOTAL EQUITY	SEK thousand	SHARE CAPITAL	OTHER CONTRIBUTED CAPITAL	ACCUMULATED LOSS	TOTAL EQUITY
Opening balance at 1/1/2019	779	126,126	-40,970	85,936	2021 loss			-31,346	-31,346
					Non-cash issue	21	6,105		6,126
2019 loss			-50,237	-50,237	New share issue	114	28,894		30,008
New share issue	281	105,677		105,958	Options		-344		-344
lssue expenses		-10,749		-10,749	lssue expenses		-2,307		-2,307
Option redemp- tion	8	3,310		3,318	Foreign currency effects			314	314
Foreign currency effects			-15	-15	Closing balance at 31/12/2021	1,203	258,410	-149,371	110,243
Closing balance at 31/12/2019	1,068	224,364	-91,222	134,211	2022 loss			-24,912	-24,912
								-24,912	
2020 loss			-27,168	-27,168	Non-cash issue	6	1,623		1,629
Options		698		698	lssue expenses		-42		-42
Foreign currency			- 1	- 1	Foreign currency effects			2,783	2,783
effects Closing balance at 31/12/2020	1,068	225,062	51 -118,339	51 <b>107,792</b>	Closing balance at 31/12/2022	1,209	259,991	-171,500	89,701
at 51/12/2020	1,000	223,002	-110,007	107,772					
					2023 loss			-22,097	-22,097
					Foreign currency			1	1

effects

Closing balance at 31/12/2023

1,209

259,991

4

-193,593

4

67,608

_	_
2	1
J	4

### PARENT COMPANY INCOME STATEMENT

SEK thousand	Note	2023	2022
	1		
Operating income			
Net sales	2.3	25,350	21,501
Cost of goods sold		-7,612	-7,430
Gross profit/loss		17,738	14,071
Operating expenses	4,5,6,7,8		
Selling expenses		-18,300	-20,534
Administrative expenses		-13,081	-12,041
Research and development expenditure		-3,034	-3,543
Other operating income		670	1,150
Other operating expenses		-921	-699
Operating profit/loss		-16,928	-21,596
Profit/loss from financial items			
Interest income and similar items	8	776	356
Interest expenses and similar items	8	-196	-117
Profit/loss after financial items		-16,348	-21,357
Tax on profit/loss for the year		-	_
PROFIT/LOSS FOR THE YEAR		-16,348	-21,357

### PARENT COMPANY BALANCE SHEET

SEK thousand	Note	2023	2022
	1		
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development expenditure	10	811	2,941
Concessions, patents, licenses, trademarks and similar rights	11	11,125	10,774
Total intangible assets		11,936	13,715
Property, plant and equipment			
Equipment, tools, fixtures and fittings	12	548	861
Total property, plant and equipment		548	861
Financial assets			
Investments in Group companies	13	48,378	46,103
Receivables from Group companies		1,779	1,252
Total financial assets		50,157	47,355
Total non-current assets		62,641	61,931
Current assets			
Inventories		3,559	973
Total inventories		3,559	973

SEK thousand	Note	2023	2022
Current receivables			
Trade receivables		4,345	3,405
Other receivables		1,139	1,343
Earned but not invoiced revenue	16	2,328	2,752
Prepaid expenses and accrued income	16	1,664	1,428
Total current receivables		9,476	8,928
Cash and bank balances		16,096	36,242
Total current assets		29,131	46,143
TOTAL ASSETS		91,772	108,074

# PARENT COMPANY BALANCE SHEET

SEK thousand	NOTE	2023	2022
EQUITY AND LIABILITIES			
Equity	18		
Restricted equity			
Share capital		1,209	1,209
Development expenditure fund		-	906
Non-restricted equity			
Share premium reserve		37,622	37,581
Option premium		-	-
Retained earnings		51,913	72,405
Profit/loss for the year		-16,348	-21,357
Total equity		74,396	90,744
Current liabilities			
Trade payables		3,979	2,584
Current tax liabilities		421	411
Liabilities to Group companies		142	405
Other liabilities		829	751
Invoiced but not earned revenue		367	99
Accrued expenses and deferred income	17	11,638	13,080
Total current liabilities		17,376	17,330
TOTAL EQUITY AND LIABILITIES		91,772	108,074

# PARENT COMPANY CASH FLOW STATEMENT

SEK thousand	Note	2023	2022
	1		
Cash flows from operating activities			
Profit/loss after tax		-16,348	-21,357
Adjustments for non-cash items			
Depreciation and amortization	9,10,11,12	3,480	3,864
Impairment losses	10	-	-
Tax		-	_
Changes in working capital			
Changes in inventories		-2,586	213
Changes in current receivables		-1,076	-3,215
Changes in current liabilities		46	5,128
Net cash from operating activities		-16,484	-15,367
Cash flows from investing activities			
Acquisitions of intangible assets, including capitalized development expenditure	9,10,11	-1,369	-1,954
Acquisitions of property, plant and equip- ment	12	-19	-354
Acquisitions/disposals of financial assets		-	-
Acquisitions of subsidiaries		-2,274	- 13,373
Net cash from investing activities		-3,662	-15,681
Cash flows from financing activities			
Transaction expenses attributable to non- cash and new share issues		_	-42
Net cash from financing activities		0	-42

SEK thousand	Note	2023	2022
NET CASH FLOW FOR THE YEAR		-20,146	-31,090
Cash and cash equivalents at start of period		36,242	67,332
Cash and cash equivalents at end of period		16,096	36,242
Supplementary cash flow statement disclo- sures			
Interest received during the year		576	183
Interest paid during the year		-	-

# PARENT COMPANY STATEMENT OF CHANGES IN EQUITY

SEK thousand	SHARE CAPITAL	DEVELOPMENT EXPENDITURE FUND	SHARE PREMI- UM RESERVE	SHARE CAPITAL IN PROCESS OF REGISTRATION	SHAREHOLD- ERS' CONTRIBUTIONS	RETAINED EARNINGS INCLUDING PROFIT/LOSS FOR THE YEAR	TOTAL EQUITY
	<b>GATTIAL</b>	Tons	OFFICELERTE	RECISINATION	Contractorions	TOK THE TEAK	Luonn
Opening balance AT 1/1/2019	779	7,649	2,445	0	0	75,672	86,546
2019 loss						-50,336	-50,336
AGM resolution			-2,445			2,445	0
New share issue	281		105,677				105,958
lssue expenses			-10,749				-10,749
Option redemption	8		3,443			-133	3,318
Development expenditure		-308				308	0
Closing balance at 31/12/2019	1,068	7,341	98,372	0	0	27,956	134,738
2020 loss						-27,257	-27,257
AGM resolution			-98,372			98,372	0
Options			698				698
Development expenditure		-2,218				2,218	0
Closing balance at 31/12/2020	1,068	5,123	698	0	0	101,289	108,179

# PARENT COMPANY STATEMENT OF CHANGES IN EQUITY

SEK thousand	SHARE CAPITAL	DEVELOPMENT EXPENDITURE FUND	SHARE PREMI- UM RESERVE	SHARE CAPITAL IN PROCESS OF REGISTRATION	SHAREHOLD- ERS' CONTRIBUTIONS	RETAINED EARNINGS INCLUDING PROFIT/LOSS FOR THE YEAR	TOTAL EQUITY
2021 loss				. <b>.</b>		-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
lssue expenses			-2,307				-2,307
Options			-344				-344
Development expenditure		-2,086				2,086	0
Closing balance at 31/12/2021	1,203	3,037	33,348	0	0	72,924	110,513
					•		
2022 loss						-21,357	-21,357
AGM resolution			-33,348			33,348	0
Non-cash issue	6		1,623				1,629
lssue expenses			-42				-42
Development expenditure		-2,131				2,131	0
Closing balance at 31/12/2022	1,209	906	1,581	0	0	87,047	90,744
2023 loss						-16,348	-16,348
AGM resolution			-1,581			1,581	0
Development expenditure		-906				906	
Closing balance at 31/12/2023	1,209	0	0	0	0	73,186	74,396

### 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 466 (245) thousand is from intra-Group purchases and SEK 735 (883) thousand from intra-Group sales.

## NOTE 4

**Leases** The Group has the following operating leases

	Group		Parent Company	
	2023	2022	2023	2022
Paid during the year	3,327	2,667	1,494	1,305
Future operating leases:				
Maturing within one year	3,408	2,720	1,698	1,494
Maturing within 2–5 years	7,161	6,589	486	1,681
Maturing later than 5 years	-	-	-	-
Total future leases	10,569	9,309	2,184	3,175

The lease payments are for cars, machinery and premises.

# NOTE 5

### Employees and employee benefit expenses

	Gro	oup	Parent Company	
	2023	2022	2023	2022
5.1 Average number of employees				
Men	11	11	9	8
Women	22	20	12	11
Total	33	31	21	19

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

5.2 Number of employees at 31 December				
Men	12	11	9	8
Women	22	24	11	13
Total	34	35	20	21
5.3 Expensed salaries and other benefits:				
Salaries and benefits – board and CEO	6,680	5,564	3,979	3,692
Salaries and benefits – other employees	14,831	14,446	11,992	11,702
Total	21,511	20,010	15,971	15,394

5.4 Social security expenses				
Pension expenses including social security contributions for CEO	938	398	398	398
Pension expenses including social security contributions for other employees	3,143	1,794	1,768	1,794
Other social security contributions	4,726	5,513	4,672	4,190
Total	8,807	7,705	6,838	6,382

	2023-12-31	2022-12-31	2023-12-31	2022-12-31
Gender distribution among senior execu- tives				
Percentage of men on board	60%	50%	60%	50%
Percentage of men among senior executives	38%	33%	43%	38%

### NOTE 6 Agreed remuneration of senior executives

Salaries and other benefits	Base salary / directors' fees	Variable remuner- ation	Other benefits	Pension expenses	Total
Carl Borrebaeck, Chairman	400	-	-	-	400
Laura Chirica, Director*	67	-	-	-	67
Anki Malmborg Hager, Director	200	-	-	-	200
lan Kimber, Director	200	-	-	-	200
Paul Yianni, Director	200	-	-	-	200
Paula Zeilon, Director	200	-	-	-	200
Total for board	1,267	-	-	-	1,267

#### CEO and other senior executives

Total for board and senior execu- tives	9,851	685	-	1,063	11,599
Total for senior executives	8,584	685	-	1,063	10,332
Other senior executives (7 people)	6,437	144	-	743	7,324
Peter Nählstedt, CEO	2,147	541	-	320	3,008

\*Left the board om 4 May 2023

#### Policies

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

The 2023 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 2023, a total of SEK 147 thousand was paid in remuneration to Ocean Capital.

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 2023, a total of SEK 33 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 2023.

# NOTE 7

### Fees and remuneration of Company's auditors

	20	23	2022		
	Group	Parent Company	Group	Parent Company	
Audit engagement, Mats-Åke Anders- son, HLB Auditoriet	425	425	434	434	
HLB Analisi, Italy	101	-	93	-	
Total	526	425	527	434	

At the AGM on 4 May 2023, 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 Analsi 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	Gro	oup	Parent Company		
	2023	2022	2023	2022	
Interest income	564	171	576	183	
Other items	200	167	200	174	
Total	764	338	776	357	

Interest expenses and similar items	Gro	oup	Parent Company		
	2023	2022	2023	2022	
Interest expenses	-37	-46	-	-	
Other items	-217	-144	-196	-117	
Total	-254	-190	-196	-117	

### NOTE 9

### Goodwill

-8,224	-3,204
_9 22/	-3.204
9	-148
-5,029	-2,920
-3,204	-136
27,217	24,001
29 217	24,851
-72	1,167
4,438	10,439
24,851	13,245
2023-12-31	2022-12-31
	24,851 4,438 -72 <b>29,217</b> -3,204 -5,029

# NOTE 10

# Capitalized development expenditure

	Group		Parent (	Company
	2023-12-31	2022-12-31	2023-12-31	2022-12-31
Opening cost	29,544	29,046	23,393	23,393
Acquisitions	-	-	-	-
Translation difference	-18	498	-	-
Closing accumulated cost	29,526	29,544	23,393	23,393
Accumulated amortization				
Opening amortization	-9,043	-5,673	-7,710	-5,579
Depreciation for the year	-3,399	-3,306	-2,130	-2,131
Translation difference	47	-64	-	-
Closing accumulated depreciation	-12,395	-9,043	-9,840	-7,710
Accumulated impairment losses				
Opening impairment losses	-12,742	-12,742	-12,742	-12,742
Closing accumulated impairment losses	-12,742	-12,742	-12,742	-12,742
Closing carrying amount	4,389	7,759	811	2,941

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 2023.

### **NOTE 11**

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

	Group		Parent C	ompany
	2023-12-31	2022-12-31	2023-12-31	2022-12-31
Accumulated cost				
Opening cost	34,932	28,226	14,068	12,114
Acquisition balance	-	4,678	-	-
Acquisitions	1,383	1,986	1,369	1,954
Translation difference	-60	42	-	-
Closing accumulated cost	36,255	34,932	15,437	14,068
Accumulated scheduled depre- ciation				
Opening depreciation	-4,584	-2,796	-3,294	-2,425
Acquisition balance	-	-13	-	-
Depreciation for the year	-2,049	-1,715	-1,018	-869
Translation difference	7	-60	-	-
Closing accumulated depreci- ation	-6,627	-4,584	-4,312	-3,294
Closing carrying amount	29,628	30,348	11,125	10,774

## NOTE 12 Equipment, tools, fixtures and fittings

	Gre	oup	Parent 0	Company
	2023-12-31	2022-12-31	2023-12-31	2022-12-31
EQUIPMENT				
Accumulated cost				
Opening cost	13,514	13,514	4,279	5,306
Acquisition balance	-	85	-	-
Acquisitions	126	484	19	264
Retirement of equipment	-	-1,291	-	-1,291
Translation difference	-40	722	-	-
Closing accumulated cost	13,600	13,514	4,298	4,279
Accumulated scheduled depreciation				
Dpening depreciation	-11,216	-10,570	-3,529	-4,041
Acquisition balance	-	-16	-	-
Retirement of equipment	-	1,291	-	1,291
Depreciation for the year	-786	-1,322	-281	-779
Translation difference	36	-599	-	-
Closing accumulated depreciation	-11,966	-11,216	-3,810	-3,529
Closing carrying amount	1,634	2,298	488	750

	Gro	up	Parent Co	ompany
	2023-12-31	2022-12-31	2023-12-31	2022-12-31
FIXTURES AND FITTINGS				
Accumulated cost				
Opening cost	1,581	1,958	453	963
Acquisitions	-	135	-	90
Retirement of fixtures and fittings	-	-600	-	-600
Translation difference	-4	88	-	_
Closing accumulated cost	1,577	1,581	453	453
Accumulated scheduled depreci- ation				
Opening depreciation	-1,304	-1,672	-342	-858
Retirement of fixtures and fittings	-	600	-	600
Depreciation for the year	-99	-157	-51	-84
Translation difference	3	-75	-	-
Closing accumulated depreciation	-1,400	-1,304	-393	-342
Closing carrying amount	177	277	60	111
Total closing carrying amount	1,811	2,575	548	861

### NOTE 13 Investments in Group companies

Parent Company	2023	2022
Accumulated cost		
Opening cost	46,103	31,101
Acquisitions	4,560	15,002
Closing accumulated cost	50,663	46,103
Accumulated impairment losses		
Opening impairment losses	-	-
Impairment losses for the year	-2,285	-
Closing accumulated impairment losses	-2,285	0
Closing carrying amount	48,378	46,103

		Company reg.		Number of	Carrying
Name	Headquarters	no.	Ownership	shares	amount
SenzaGen Inc.	North Carolina, USA	C3870650	100%	1,000 shares	84
VitroScreen S.r.l.	Milan, Italy	MI-1653696	100%	15,000 quotas	40,917
ToxHub S.r.l.	Rome, Italy	MI-2690194	100%	10,000 quotas	7,376

### NOTE 14 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	24,188,325	0.05	1,209,416
Number/quotient value of shares at end of year	24,188,325	0.05	1,209,416
		2023	2022
Earnings per share			
Earnings per share (SEK)		-0.91	-1.03
Fully diluted earnings per share (SEK)		-0.91	-1.03

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.

	2023	2022
Number of outstanding shares (thousands)		
Weighted average during the year	24,188	24,085
At the end of the year,	24,188	24,188

### NOTE 15 Pledged assets and contingent liabilities

	2023	2022
For the Group's own liabilities		
Floating charges	7,500	1,000
Contingent liabilities	None	None

Floating charges refer to an unpledged mortgage deed with Skandinaviska Enskilda Banken (SEB).

### NOTE 16 Prepaid expenses and accrued income

	Gro	oup	Parent Company		
	2023-12-31	2022-12-31	2023-12-31	2022-12-31	
Prepaid rent	390	570	386	363	
Prepaid insurance	198	162	97	162	
Earned but not invoiced revenue	2,328	2,752	2,328	2,752	
Other items	1,229	903	1,181	903	
Total	4,145	4,387	3,992	4,180	

### NOTE 17 Accrued expenses and deferred income

	Gro	oup	Parent Company		
	2023-12-31	2022-12-31	2023-12-31	2022-12-31	
Accrued employee benefit expenses	2,225	2,604	1,941	2,399	
Additional consideration – acquisi- tion	8,877	10,015	8,877	10,015	
Other items	827	769	820	766	
Total	11,929	13,388	11,638	13,180	

### NOTE 18 Equity

At 31 December 2023, 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 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 period is 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.

#### 2023/2026 stock option plan

The AGM on 4 May 2023 resolved to approve the board's proposal to issue a maximum of 1,015,000 stock options, as a result of which the Company's share capital may increase by a maximum of SEK 50,750.

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 200,000 options. Members of Group Management and key personnel comprising up to eleven positions will each be offered to subscribe for a maximum of 50,000 options, altogether comprising a maximum of 500,000 options.

Other employees and consultants considered key personnel in the Group, comprising twenty-three individuals, will be offered to subscribe for between 10,000 and 25,000 options each, altogether comprising a maximum of 315,000 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 19 April 2023 to 3 May 2023. 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 2026 to 30 September 2026 or the earlier date set out in the option rules.

The maximum dilutive effect of the 2023/2026 series is estimated to be no more than 4% 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

lan Kimber Director Anki Malmborg Hager Director

Paul Yianni Director Paula Zeilon Director

Peter Nählstedt CEO

The annual report and consolidated financial statements were adopted by the board on 21 March 2024.

My auditor's report was submitted on 21 March 2024.

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 redemp- tion	5,850	117,000	778,900	15,578,000	0.05
2019	Option redemp- tion	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
2023	No events	-	-	1,209,416	24,188,325	0.05

Shareholders <sup>1</sup>	Number of shares	Percentage of share capital and votes
Carl Borrebaeck	1,694,000	7.0
Malin Lindstedt	1,614,845	6.7
Ålandsbanken in place of owner	1,402,058	5.8
Suad Nimani	1,038,442	4.3
Hans Westberg	972,500	4.0
Nordnet Pensionsförsäkring AB	857,186	3.5
Avanza Pension	772,873	3.0
Futur Pension Försäkringsaktie- bolag	737,033	3.0
Jonas Pålsson via company	691,472	2.9
Jarl Ingvar Andersson	685,000	2.8
Total for 10 largest shareholders	10,465,409	43.3
Other shareholders	13,722,916	56.7
Total	24,188,325	100.0

<sup>1</sup>The total number of shareholders at 29/12/2023 was 2,869 (3,047) (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 2023 financial year. The Company's annual report and consolidated financial statements are presented on pages 28–51 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 2023, 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 2023 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 effective-ness of internal controls.

• I also evaluate the appropriateness of the accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors and CEO.

• I form an opinion on the suitableness of application of the going concern assumption by the board of directors and CEO in the preparation of the annual report and consolidated financial statements. On the basis of the audit evidence obtained, I also form an opinion as to whether there is any material factor of uncertainty with respect to such events or circumstances as could lead to significant doubt about the Company and Group's ability to continue business. If, in my opinion, there is a material factor of uncertainty, my audit report must call attention to the disclosures in the annual report and consolidated financial statements on this material factor of uncertainty or, if such disclosures are insufficient, I must modify my opinion on the annual report and consolidated financial statements. My opinions are based on the audit evidence obtained up to the date of the auditor's report. However, future events or circumstances may result in a company and group being unable to continue business

# AUDITOR'S REPORT

• 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 2023 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,

2024-03-21

*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 3,000 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 51.

Four shareholders representing 9% of the total shares and votes in the Company attended SenzaGen's AGM on 4 May 2023 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 2024 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 2023 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 2023 AGM re-elected Carl Borrebaeck, Ian Kimber, 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 56.

#### 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 4 May 2023. The chairman evaluates the work of the board once a year.

#### Board meetings

The SenzaGen Board of Directors held 10 meetings at which minutes were taken during the year; one was the Statutory Board Meeting. 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 2023 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 2023 AGM for a term lasting until 2024.

#### **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 4 May 2023. 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 57.

#### Remuneration of the CEO and other senior executives

The 2023 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 Laura Chirica*	10 of 10 3 of 10
lan Kimber	8 of 10
Ann-Christin Malmborg Hager	10 of 10
Paula Zeilon	10 of 10
Paul Yianni	10 of 10
* left the board on 4 May 2023	

# **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 Health translational cancer research center at Lund University. He is an entrepreneur and founded SenzaGen AB and several other life science companies, including Immunovia AB and BioInvent International AB. He is also a founding mentor for the Nordic Mentor Network for Entrepreneurship (NOME), a member of the Roval 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, the Royal Swedish Academy of Engineering Sciences (IVA) Gold Medal in 2012, and the Biotech Builder Award in 2017.

#### Other significant appointments:

Board chairman of PainDrainer AB and CB Ocean Capital AB.

#### Shareholding:

1,707,571 shares (privately and through related parties).

#### Independence:

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



ANKI MALMBORG HAGER Director since 2019. Född1965.

#### Education and experience:

PhD in immunotechnology, MSc in chemical engineering, Pharma MBA.

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

#### Other significant appointments:

Board director at NanoEcho AB, Lead Biologics International AB, Avena Partners AB and Hager Consulting AB.

#### Shareholding:

385,000 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:

7,800 shares and 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: 60,000 shares and 15,000 stock options.

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

# 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 and BSc in business administration from Lund University.

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:

36,700 shares and 300,000 stock options.



MARIANNE OLSSON VP Finance.

Employee since 2016. Born in 1961.

#### **Education and experience:** Certified Financial Manager via FAR.

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

#### Other significant appointments: None.

#### Shareholding:

114,285 shares and 150,000 stock options.

Shareholdi



ANNA CHÉROUVRIER HANSSON VP Business Development & Strategy.

Employee since 2017. Born in 1973.

#### Education and experience:

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

Anna Chérouvrier Hansson has extensive experience in marketing, sales and business development at companies including Camurus, Novo Nordisk, Gambro and Du-Pont. 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 140,000 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, Cellavision and Enzymatica.

#### **Other significant appointments:** Board director at Medimi AB.

#### Shareholding:

1,000 shares and 150,000 stock options.

# SENIOR EXECUTIVES



ANDY FORRERYD VP Sales.

Hired in 2017 and part of management team since 2022. Born in 1984.

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

Andy Forreryd has many years of experience in the field of *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 40,000 stock options.



HENRIK JOHANSSON Chief Scientist.

Employee since 2014 and part of management team since 2020. Born in 1982.

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

Henrik Johansson has more than 15 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<sup>®</sup> technology platform, which was first described in detail in his doctoral thesis.

Other significant 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 75,000 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, and 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 100,000 stock options.

# FINANCIAL SUMMARY

			0004		
	2023	2022	2021	2020	2019
Net sales, SEK thousand	49,870	41,770	15,422	7,958	2,724
Capitalized developed ex- penditure, SEK thousand	-	_	31	334	1,110
Profit/loss for the year	-22,097	-24,912	-31,346	-27,168	-50,237
		-			
Equity ratio (%)	70	75	82	97	94
Quick ratio, %	115	179	332	2,477	2,173
Equity, SEK thousand	67,608	89,701	110,243	107,792	134,211
Average number of em- ployees	33	31	21	18	22
Number of employees at year-end, converted to full-time equivalents	34	35	31	17	23
Average number of shares	24,188,325	24,085,484	21,808,849	21,357,636	16,175,772
Number of shares at end of period	24,188,325	24,188,325	24,064,916	21,357,636	21,357,636
Earnings per share, SEK <sup>1</sup>	-0.91	-1.03	-1.35	-1.27	-3.11
Fully diluted earnings per share, SEK <sup>2</sup>	-0.91	-1.03	-1.35	-1.27	-3.11
Equity per share (SEK)	2.80	3.71	4.58	5.05	6.28
Dividend per share, SEK	-	-	-	-	-

<sup>1</sup> Based on average weighted number of outstanding shares.

<sup>2</sup> 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

15 May 2024 January-March 2024 Interim Report
15 May 2024 Annual General Meeting
15 August 2024 January-June 2024 Interim Report
8 November 2024 January-September 2024 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.

#### 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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- 4 Alternatives to Animal Experimentation 2018 ncbi.nlm.nih.gov/ pub-med/30008008.
- 5 Kalorama International 2018: *In Vitro* Toxicology.
- 6 Swedish Medical Products Agency, Förbud mot djurförsök.
- 7 Swedish Fund for Research Without Animal Experiments (Forska utan djurförsök)
- 8 TÜV SÜD.
- 9 International Organization for Standardization.
- 10 Swedish Board of Agriculture.
- 11 Kalorama Information 2018, In Vitro Toxicology.
- 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/.
- 15 Validation study, OECD Test Guideline Program (TGP no. 4,106). Johansson H. et al. Toxicological Sciences 2019.



# $S \equiv NZA$ $G \equiv N$

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

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