

# SenzaGen

Sector: Medtech

## The Non-Animal Alternative

Redeye initiates coverage of SenzaGen, a Swedish commercial-stage MedTech company offering high-performance in-vitro technology tests that are set to capitalize on the trend toward animal-free testing in cosmetics, medical devices, chemicals, and pharmaceutical industries. Its updated growth-oriented commercial strategy, driven by an increased effort for acquisitions, offers a compelling case with 63% upside to our Base Case.

### Non-animal testing method with strong scientific evidence

SenzaGen's comprehensive offering includes the GARD platform that classifies the sensitization level of substances with a broad applicability and accuracy of up to 94%. It delivers better and more detailed test results than both other non-animal testing methods and the most popular animal test, LLNA (in-vivo). SenzaGen's technology contributes to a safer, more ethical, and sustainable testing method that can reduce the use of animals in the cosmetics, chemical, pharmaceutical, and medical devices industries.

### OECD validation

An OECD validation on GARDskin is crucial if SenzaGen fully lever its innovation. This validation would increase its available market significantly and allow SenzaGen to meet the OECD validation requirements of its customers, opening the door to better commercial opportunities. With impressive study results and a positive opinion from ESAC in 2021, we expect a favorable decision this year.

### Acquisition-driven growth

The company has changed its strategy in recent years to now focus on both organic and acquisition-driven growth. In 2021, SenzaGen completed its first acquisition: VitroScreen, an Italian company offering in-vitro pre-clinical testing. We expect SenzaGen to acquire more companies focusing on non-animal testing methods and additionally other innovative methods to meet new endpoints. We believe any target companies will be profitable, with sales up to SEK 75m.

### 63% upside

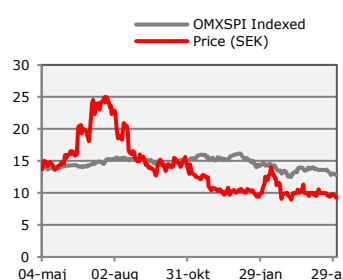
We argue that the current share price of SEK 9.8 does not reflect the long-term potential in SenzaGen. Our DCF model (14% WACC) suggests a Base Case of SEK 16, with Bear and Bull cases of SEK 5 and SEK 27, respectively. We expect the gap to our Base Case to be closed in 12 months thanks to the OECD validation and half-year reports.

Key Financials (SEKm)	2021	2022E	2023E	2024E
Net Sales	15	44	61	86
Sales Growth	94%	183%	40%	41%
EBITDA	-32	-19	-12	-1
EBITDA margin	neg	neg	neg	neg
EBIT	-32	-24	-18	-7
EBIT Margin	neg	neg	neg	neg
EV/Sales	12.2	4.3	3.1	2.2

### FAIR VALUE RANGE

BEAR	BASE	BULL
5	16	27

### SENZA VERSUS OMXSPI



### REDEYE RATING



### KEY STATS

Ticker	SENZA
Market	First North
Share Price (SEK)	9.80
Market Cap (SEKm)	236
Net Debt 2022E (SEKm)	-44
Free Float	89%
Avg. daily volume ('000)	6

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## Investment Thesis

### Case: Ethical testing method

SenzaGen exposes investors to the in-vitro toxicology testing market. Following a bumpy ride for shareholders, with a downward share price trend over the past couple of years, the company has changed its strategy to also focus on acquisition-driven growth. In 2021, it acquired its first entity, VitroScreen. Despite its still relatively low sales (FY'21 SEK 15m), we expect sales to increase at a CAGR of 77 percent in 2022-2024 taking sales to SEK 86m. This growth is underpinned by a trend favoring non-animal testing as regulatory requirements are changing where we believe that SenzaGen's testing methods can become well-positioned in its targeted industries.

### Evidence: Great long-term potential

We expect OECD to validate SenzaGen's GARDskin this year, unlocking its great sales opportunities. Currently, around 50 percent of sales stem from existing customers, and we believe that an OECD validation will result in a higher percentage of recurring sales as larger customers can use GARDskin in both product development and use the data in product filing. In 2013, the EU banned animal testing in the development of cosmetic products, and we anticipate a scenario of more bans in other industries in the future. Because of this, we judge that animal testing is set to decrease because of potential future bans and that in-vitro testing methods become more common since it is cheaper, more cost-effective, and provide more reliable test results than in-vivo.

#### Supportive analysis: Scientific evidence

SenzaGen offers a comprehensive product portfolio, covering what is necessary to evaluate a substance's sensitization. Studies have shown that SenzaGen's products have higher accuracy and provide unique features compared to competitors.

	GARDskin	h-Clat	KeratinoSens	LLNA	DRPA
Accuracy	86-94%	76%	75-90%	70-75%	82%

Source: SenzaGen, Redeye Research

Studies show that one of SenzaGen's main products, GARDskin, has the highest accuracy in determining if a substance should be classified as a sensitizer or not. The GARD technology uses up to 200 biomarkers (measurable indicators) and machine learning to generate deeper and more comprehensive test results and includes complex mixtures that traditionally have been difficult to test. This helps cosmetics, medical devices, pharmaceutical, and chemical companies to develop safer products.

As studies have shown the advantages of SenzaGen's products, we believe the company can become well-positioned in non-animal testing market.

### Challenge I: Acquisition strategy

SenzaGen focuses on both organic and acquisition-driven growth. We assume that the company intends to acquire profitable companies with sales up to SEK 75m that offer non-animal testing methods and innovations that can expand its available market. Naturally, there is a risk related to acquisitions through several aspects, all with the potential to destroy rather than create value. Thus, finding the right companies, and integrating these successfully, could pose challenges – especially for a company that has limited experience in acquisitions.

**Challenge II: Proof of sales**

Another challenge for SenzaGen is to prove that it can increase sales. The company is still in the early stages and increasing sales could be challenging. We consider the next couple of years crucial for SenzaGen to prove that its testing methods deliver results by attracting large companies and keeping them recurring. In our Base Case, we estimate that the company will be profitable from 2025 with sales of SEK 112m, which is SEK 97m higher than net sales in 2021, a challenging but doable task, in our opinion.

**Valuation: Current valuation does not reflect the potential**

Since the share's all-time high in 2018, its performance has been severely negative, falling around 86% to date. Our current Base Case scenario suggests a valuation of SEK 16, 63% higher than the current share price of SEK 9.8. Two of the key assumptions in our Base Case are a favorable decision by the OECD on GARDskin this year and that its acquisition-oriented strategy results in significant sales growth in the years ahead. Thus, we believe that the current share price levels do not reflect the changed case we have identified in SenzaGen. As we advance, and the company delivers according to its new strategy, we expect the market to re-evaluate the equity story. In addition to our Base Case, our Bull Case of SEK 27 also assumes OECD validation and a faster ramp-up in sales, while our Bear Case of SEK 5 assumes the OECD requires more data, with resulting lower sales growth than in our Base Case.

## Catalysts

### OECD validation

A key objective for SenzaGen has been OECD validation and inclusion in test guidelines. Validation would increase the potential available market, adding potential customers that require validated testing methods in their product development and registrations, which would expand the customer base, in both the short and long term. Many potential customers demand OECD validation, which can be seen as a safety license in the OECD states. We believe validation is highly likely for GARDskin considering the competitors that have received validation and the positive opinion from the ESAC (the scientific advisory committee of the EURL ECVAM, the EU Reference Laboratory for alternatives to animal testing) last year.

**Time frame:** During 2022

**Impact:** Moderate to major

### Acquisitions

SenzaGen's strategy is based on both organic and acquisition-driven growth. We believe SenzaGen will target profitable companies with up to approximately SEK 75m in revenues that operate in the non-animal testing industry, preferably also offering technology that would expand the markets SenzaGen targets. As such, acquisitions further bolstering the outlook for SenzaGen could be a catalyst for the share price.

**Time frame:** Ongoing

**Impact:** Moderate to major

## Counter Points

### Delay or non-validation by OECD

In 2022, SenzaGen can potentially receive validation from the OECD on its GARDskin product. Such processes always come with a risk that the decision is delayed or proves negative. Either scenario would negatively impact future sales and decrease the potential customer base as many larger companies see validation as necessary before they can consider buying tests. However, we believe the risk for a delay or unfavorable decision is low due to strong study results and a positive opinion from ESAC, but it is essential to point this out since either scenario would result in poor share price performance.

**Time frame:** During 2022

**Likelihood:** Low

### Disappointing sales

As SenzaGen is currently in an early commercialization phase, there is a risk that future sales do not live up to expectations. The company is still a few years away from being profitable, and disappointing sales would result in a higher likelihood of additional funding requirements and poor share performance.

**Time frame:** Ongoing

**Likelihood:** Medium

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## Company Description

Founded in 2010 by professors Carl Borrebaeck and Malin Lindstedt from Lund University, SenzaGen develops, sells, and performs non-animal testing to analyze substances' allergenicity. The GARD tests use human cells and machine learning rather than animals to assess whether a substance causes an allergic reaction on the skin or in the respiratory tract. Except the GARD platform, SenzaGen performs regulatory tests for skin irritation and corrosion in its GLP-certified laboratory. Beyond that, the company also perform skin irritation and cytotoxicity tests and services for medical devices and advanced 3D tissue models to reflect human biology through the acquired VitroScreen's ORA platform. The primary purpose of the in-vitro technology is to contribute to a safer, more ethical, and sustainable testing, reducing animal testing in the cosmetics, chemicals, medical devices, and pharmaceutical industries.

Previous studies have shown that LLNA (animal testing) offers 70-75% accuracy when testing a substance's allergenicity. The GARD tests measure approximately 200 biomarkers and allow for up to 94% accuracy.

The majority of SenzaGen's sales stem from its direct sales channels for tests at its own laboratory at company headquarters in Lund, Sweden, and the rest from distributors and contract research organizations (CROs) in Germany and the US.

Today, SenzaGen employs 31 staff. The company was listed on Nasdaq First North in 2017, at SEK 19.40 per share. Since then, the share has had a bumpy ride, reaching an all-time high of nearly SEK 70 in 2018 before dropping to the current SEK 9.8 after a downward trend over the past few years.

Year	Historical Highlights
2010	• SenzaGen is founded by Professor Carl Borrebaeck and Professor Malin Lindstedt
2013	• The European Union ban animal testing in the cosmetic industry
2014	• SenzaGen AB is incorporated
2015	• GARDskin is launched
2016	• OECD includes GARD in OECD test guideline program's validation process • A subsidiary, SenzaGen Inc started in California in order to advertise and sell products • The company signs distribution agreements with players in Europe, the USA and Asia
2017	• Signed co-operation agreement with AstraZeneca for further development of GARDair • GARDpotency is scientifically validated and pilot launch • Signed co-operation agreement with one of the largest CRO's in the world - Charles River in the UK
2018	• Launch of GARDair • Signed global licensing agreement with Eurofins Biopharma product testing Munich • Peter Nählstedt becomes a board member
2019	• Signed distribution agreement with VitroScreen • Expansion of product portfolio with GARDskin-medical device • Raised SEK 106 million via a directed share issue
2020	• Signed distribution agreement with Danske Teknologisk Institut (DTI) • GARDskin and GARDair tests order of SEK 1.2 million • SenzaGen and US Research Institute for Fragrance Materials (RIFM) signed a collaboration agreement to develop next-gen tests for photosensitization
2021	• Positive ESAC opinion on GARD, a step closer to OECD validation • Peter Nählstedt becomes CEO • Acquisition of VitroScreen • Order of SEK 1.65 million from one of the largest cosmetics companies in the world • GARDskin order of SEK 0.7 million from one of the largest pharmaceuticals companies in the world • Expanded regulatory test services within in-vitro skin toxicology

Source: Company data, Redeye Research

## Management, Board, and Ownership

### Ownership

Both founders of SenzaGen, Carl Borrebaeck and Malin Lindstedt, are large shareholders, with approximately seven percent ownership each. We see this as positive, as also Professor Borrebaeck remains involved in the company in his role as chairman. Among the top ten shareholders, we note not only a majority of private investors but also institutional investor Fjärde AP-fonden. As time passes and the company progresses with its commercial strategy, we hope to see more institutional names appearing in the shareholder list.

### Top 10 shareholders

#	Name or institution	No. of shares	Capital (%)	Votes (%)	Country
1	Carl Borrebaeck	1 690 000	7.02%	7.02%	Sweden
2	Malin Lindstedt	1 614 845	6.71%	6.71%	Sweden
3	Suad Nimani	955 340	3.97%	3.97%	Sweden
4	Nordnet Pensionsförsäkring	906 936	3.77%	3.77%	Sweden
5	Futur Pension	747 033	3.06%	3.06%	Sweden
6	Hans Westberg	702 207	2.92%	2.92%	Sweden
7	Avanza Pension	663 744	2.76%	2.76%	Sweden
8	Jarl Ingvar Andersson	641 000	2.66%	2.66%	Sweden
9	Fjärde AP-fonden	640 503	2.66%	2.66%	Sweden
10	3 RS Management and Consulting ApS	590 358	2.45%	2.45%	Denmark
Others		14 912 950	62.0%	62.0%	

Source: Holdings, Redeye Research

### Management and board

Dr. Borrebaeck is a professor at the department of immunotechnology and program director of the CREATE translational cancer research center at Lund University. He has founded other life science companies such as Immunovia AB and Bioinvent International AB. We see it as positive that Dr. Borrebaeck has experience from other life science companies and that the board in general has great knowledge of the sector.

The management team is solid, in our view, bringing experience from other companies in the sector. CEO Peter Nählstedt originally joined as a board member but stepped in as CEO in Q3 2021. His most recent operational assignment was as CEO of Probi AB between 2014 and 2018, where he increased sales from SEK 135m to more than SEK 600m and expanded the employee base from 26 to 167.

### Management and board ownership

Management					Board of directors				
Name	Shares	Ownership (%)	Position	Warrants	Name	Shares	Ownership (%)	Position	Warrants
Peter Nählstedt	23 919	<0.1%	CEO	25 000	Carl Borrebaeck	1 698 571	7.02%	Chairman	
Marianne Ohlsson	114 285	0.5%	VP Finance	50 000	Laura Chirica	-		Member	
Anna Chérourvriér Hansson	19 153	<0.1%	VP Sales & Business Development	65 000	Anki Malmborg Hager	383 000	1.6%	Member	
Tina Dackemark Lawesson	1 000	<0.1%	VP Marketing & Communications	65 000	Ian Kimber	1 500	<0.1%	Member	
Henrik Johansson	526	<0.1%	Chief Scientist	10 000	Paul Yianni	20 000	<0.1%	Member	15 000
Åsa Nyhlén	6 300	<0.1%	VP Operations	50 000	Paula Zeilon	6 000	<0.1%	Member	10 000
Helen Olsson	5 000	<0.1%	VP HR						
Marisa Meloni	378 232	1.5%	CEO VitroScreen						

Source: SenzaGen, Redeye Research

## Stock Performance

On September 21, 2017, the SenzaGen stock was listed on Nasdaq First North at a subscription price of SEK 19.40, raising SEK 90m before costs.

The share price reached an all-time high of SEK 69 in August 2018 thanks to a good flow of positive news related to commercial progress and according to Roberts (2018) that GARDskin is the best non-animal testing method in the industry. The massive share price rise ended when the EURL ECVAM's sustainability advisory committee validation process for GARDskin was delayed in September 2018, and it has not yet recovered.

SenzaGen has issued new shares twice since its IPO: a combination of a directed issue of SEK 64m and a rights issue of some SEK 42m, totaling SEK 108m in November 2019; and a directed issue of SEK 30m in October 2021 to finance the acquisition of VitroScreen.

Naturally, the impact of the COVID-19 pandemic has hindered the company's plans considerably and delayed the anticipated ESAC validation, but as societies begin to return to normal, we see an improved outlook for SenzaGen to execute its strategy.

### Stock performance and highlights



Source: Yahoo Finance, Redeye Research



## Product Portfolio

SenzaGen's product portfolio includes non-animal testing methods focusing on skin and respiratory allergy. The first mentioned include GARDskin, Gardskin Medical Devices, GARDpotency and GARDskin Dose-Response which analyze a substance's allergenic effect on the skin. GARDair focuses on the allergenicity in the respiratory tract. All the tests in the GARD platform perform deep and accurate test results that helps companies in product developments.

**SenzaGen's GARD platform**

Skin Allergy	Respiratory Allergy
GARDskin	GARDair
GARDskin Medical Devices	
GARDpotency	
GARDskin Dose-Response	

Source: SenzaGen, Redeye Research

### GARD®Skin

The purpose of GARDskin is to assess whether a chemical substance could cause skin allergies. The target group is companies in the cosmetics, chemicals, and pharmaceuticals industries. GARDskin's proven accuracy of up to 94%, broad applicability and quantitative potency assessment feature mark the test as the most reliable on the market. It helps developers, producers, and society ensure with a high degree of certainty that products are free of allergies.

Traditionally, complex mixtures of substances have been challenging to analyze, increasing the risk of allergic reactions to developed products. GARDskin supports these types of substances and pure chemicals, increasing their demand on the market. In 2021, the Environmental Sustainability Advisory Committee (ESAC) published a report that the GARDskin assay meets the requirements of the EU Reference Laboratory for alternatives to animal testing (EURL ECVAM) for reliability testing in preparation for CE marking. The GARDskin test is thus science- and evidence-based and can be transferred to other laboratories with the same performance regardless of who conducts the test. In the report, the ESAC recommended that the OECD includes GARDskin on its list of internationally agreed test methods. The expert opinion from the ESAC takes GARDskin one step closer to OECD validation, with a decision expected during 2022. Issued OECD test guidelines would allow customers to use GARD test results in product registrations. It can also be seen as a safety license in OECD states, resulting in a more attractive test method that can expand SenzaGen's current customer base.

### GARDskin's advantages



Source: SenzaGen

### GARD®skin Medical Device

GARDskin Medical Device is an expanded application domain of GARDskin that offers an in-vitro alternative for skin sensitization testing as a part of the Biological Evaluation of Medical Devices. The assay can directly test medical devices and solid materials to classify whether they are a skin sensitizer or non-sensitizer. The test is the first on the market developed specifically for medical devices that require a risk assessment for skin allergies before they receive regulatory approval. Medical devices are affected by regulatory frameworks changes that are expected to increase the demand for alternative test methods. For example, the global ISO standards and the EU Medical Device Regulation's (MDR) increased requirements for product safety are included in the regulatory changes.

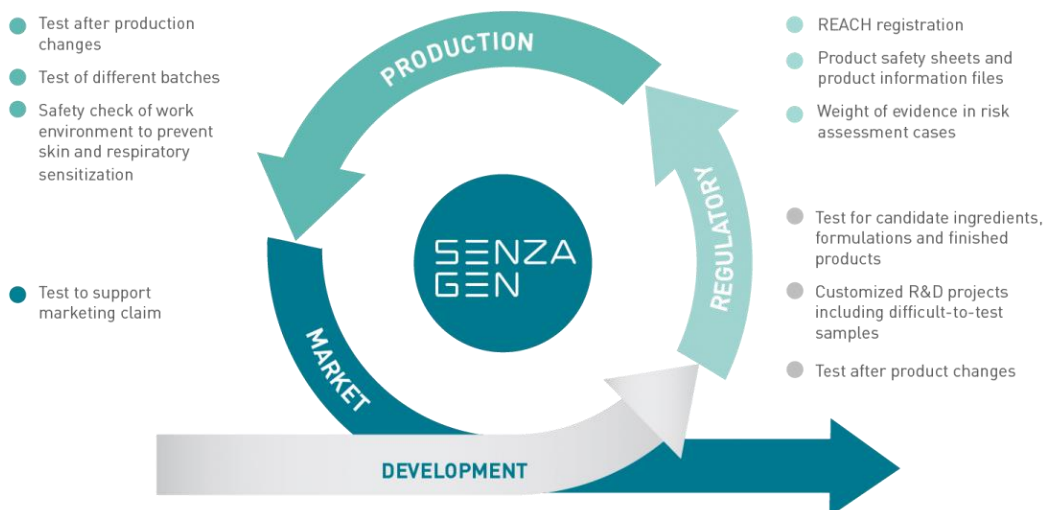
### GARD®potency

GARDpotency is an add-on test to GARDskin but can also be used independently. Should the results from the GARDskin test show that a substance creates an allergic reaction (sensitization), GARDpotency can be used to classify if the substance should be categorized as 1A (strong sensitizer) or 1B (weak sensitizer). This is a REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals) requirement for companies that develop cosmetics and pharmaceutical products. Approved regulatory tests for potency classification on the market are performed on animals. From an ethical perspective, GARDpotency is a better option, and studies comparing results show that GARDpotency has a predictive accuracy of 88% in categorizing between strong or weak sensitizers.

### GARD®skin Dose-Response

GARDskin Dose-Response is an expanded application domain of GARDskin with the primary purpose of providing information on the dose at which a substance causes allergy. This enables companies in the cosmetics, pharmaceutical, and chemical industries to identify the highest possible quantity of a chemical that can be included in their products without causing an allergic reaction.

### SenzaGen's offering



Source: SenzaGen

**GARD®air**

GARDskin Medical Device, GARDpotency, and GARDskin Dose-Response are all expanded application domains of GARDskin to analyze different substances' allergic effects on the skin. GARDair is used similarly but focuses on whether chemical substances could cause respiratory allergies in product candidates. The test is recommended in the research and development process and is the first of its type on the market. The chemical impact on the respiratory system is essential to evaluate for manufacturing in the cosmetics, chemical, and pharmaceutical industries, as well as for specific groups such as painters and hairdressers. The development of GARDair has been supported by the EU's SME program Horizon2020. GARDair uses 28 biomarkers compared to 200 in the other GARDskin tests. Study results show that GARDair's specificity is 95 percent, which means that there are few false-positive results, meaning that most of the substances classified as sensitizers can accurately be excluded from the products. On the other hand, the study results show that the overall accuracy is 74 percent and the sensitivity is 53 percent, which means close to a 50:50 likelihood that a substance classified as a non-sensitizer should be classified as a sensitizer. Therefore, many customers have used GARDair as an opt-out tool because of its high specificity.

Currently, GARDair is the only non-animal testing method for analyzing respiratory allergies from substances. At the same time, there are no regulatory requirements for SenzaGen and with interest from ECVAM which has started to focus on air and air requirements in the labor market, we judge that GARDair could be a great product for SenzaGen in the long term.

**Study results for GARDair**

<b>Accuracy</b>	<b>74%</b>
<b>Sensitivity</b>	<b>53%</b>
<b>Specificity</b>	<b>95%</b>
<b>Within Laboratory Reproducibility</b>	<b>52-72%</b>
<b>Between Laboratory Reproducibility</b>	<b>79%</b>

Source: SenzaGen, Redeye Research

**GLP Regulatory toxicity testing**

In 2021, SenzaGen expanded the product portfolio by offering testing services beyond skin sensitization to include irritation and corrosion because of an increased demand on the market. The regulatory tests are approved as OECD guidelines to identification of irritants/non-irritants and corrosive/non-corrosive substances. The testing is performed in the laboratory in Lund which is one of the few Nordic laboratories that are GLP-certified.

In 2022, SenzaGen provided an expanded and more complete in-vitro technology test offering for the large medical devices market. The expanded offering includes skin irritation and cytotoxicity tests and services for medical devices that complement the GARD platform. The tests are also non-animal tests for biological evaluation, identification of medical devices, and classification under the EU Medical Device Regulation.

## VitroScreen

On October 28, 2021, SenzaGen entered into an agreement to acquire 100 percent of the shares in VitroScreen, a CRO company based in Milan, Italy. VitroScreen has two decades of experience committed to alternatives to animal testing in in-vitro toxicology and pre-clinical testing across the following businesses:

- GLP-certified facility for in-vitro toxicology, including regulatory testing
- Pre-clinical in-vitro testing service unit for safety and efficacy testing on human 3D tissue models for the pharmaceutical, cosmetics, chemical, and nutritional industries
- In-vitro consulting unit providing advice on regulatory in-vitro toxicology strategies
- In-vitro Innovation Center with the ORA platform to produce human organoids and spheroids and microbiome research.

SenzaGen acquired 100 percent of the shares in VitroScreen for EUR 2.6m, of which EUR 2.0m was in cash and EUR 0.6m in consideration shares. The subscription price for the shares was determined to be SEK 14.71, based on the average share price during 7-26 October 2021. The payment also includes earn-out payments to be paid during 2022-2024 if specific financial targets are achieved. The first two payments are EUR 0.5m each, and the last payment is EUR 400,000, totaling acquisition costs of up to EUR 4m if all the financial targets are reached.

We consider the acquisition positive for SenzaGen as VitroScreen's product portfolio expands its available market, and we are encouraged that VitroScreen has a history of profitable growth and expertise in the sector. The company reported sales of EUR 1.6m in 2020 and represented SEK 3.3m of SenzaGen's 2021 year-end report, which only included VitroScreen's November and December sales. We also believe it positive that the two companies have previously collaborated for a few years through a distribution agreement signed in 2019. Additionally, Dr. Marisa Meloni (the founder of VitroScreen) brings experience and knowledge in the industry to SenzaGen.

VitroScreen's GLP-certified laboratory provides toxicology services for bio-equivalence, hazard identification, and regulatory classification in different industrial contexts such as chemicals, pharmaceuticals, pesticides, plant protection products, etc. It also has a pre-clinical expertise unit that offers state-of-the-art technologies, 3D human tissues, mucosae, and microtissue models with very high proximity to human physiology.

Owing to the ongoing introduction of new safety requirements as part of many regulations, VitroScreen also offers an in-vitro consultancy unit with the aim of providing its customers with high-level in-vitro testing strategies for hazard and risk assessment, coupled with an independent pharmaco-toxicological expertise judgment.

Its in-vitro innovation center operates as an outsourcing unit for R&D projects in areas as diverse as body barriers and body organs for the pharma, cosmetics, nutritional, and chemical industries. It includes the Histo-morphology platform, which in 2020 made VitroScreen the first Italian CRO to offer services by Leica THUNDER Imager System, a new class of instruments designed specifically for high-quality, fast imaging of thick 3D specimens under optimal physiological conditions. Microbiome research is another part of the innovation center, focusing on the host response and bacteria to use relevant models to assess bacterial interactions with living tissue/organs to mimic real sites where tissue and microbiota interactions might occur. The last area of the innovation center is the VitroScreen ORA platform.

**VitroScreen ORA®**

VitroScreen is leading the innovation in pre-clinical testing based exclusively on 3D human advanced tissue models, offering its services to customers in the pharmaceutical, medical devices, cosmetics, chemical, agrochemical, and nutritional industries as more biologically relevant alternatives to animal testing. ORA is a miniaturized organ and tissue-specific 3D model mirroring phenotypic characteristics of the donor's cells and related metabolic pathways.

**The eight models in the ORA platform**

	Cell type	Key features and applications
<b>DERMIS</b>	HDFs: Primary Human Dermal Fibroblasts (from single donors of different ages)	<ul style="list-style-type: none"> <li>• ECM proteins different deposition with young or old donors</li> <li>• Targeting genes of aging process and dermal matrix deposition and remodelling</li> <li>• Atrophy, bio-revitalisation, personalized care</li> <li>• Co-cultures with endothelial cells, monocytes</li> <li>• Inflammatory model</li> </ul>
<b>SKIN</b>	HDFs and HKs: Primary Human Dermal Fibroblasts and Primary Human Epidermal Keratinocytes.  co-culture	<ul style="list-style-type: none"> <li>• Early screening of differentiation and barrier formation</li> <li>• Cross-talk and molecular pathways between dermis-epidermis compartments</li> </ul>
<b>HAIR FOLLICLE AND DERMOPAPILLA</b>	HPDCs and HFKs: Human Hair Follicle Dermopapillar Cells and Human Hair Follicle Keratinocytes.  co-culture	<ul style="list-style-type: none"> <li>• Unique in-vitro model to study hair cycling, anagen/catagen transition and suitable to follow catagen involution</li> <li>• It can be used as an isolated dermopapilla or as a hair follicle with surrounding HFKs</li> </ul>
<b>ADIP</b>	Primary Human Subcutaneous Pre-adipocytes;  Human iPSC-derived MSCs	<ul style="list-style-type: none"> <li>• Metabolic studies</li> <li>• Metabolic disorders simulation and long-term exposures</li> <li>• Stress models: inflammation, differentiation and fibrosis</li> <li>• Lipolysis, adipogenesis, lipo-boosting, lipid destock: slimming, plumping, resculpting</li> <li>• Applicable to pre, pro, probiotics (customized models)</li> </ul>
<b>CORNEAL STROMA</b>	HKs: Primary Human Keratocytes	(keratoconus, keratitis)
<b>PROSTATE</b>	HPrECs and PrSMCs: Human Primary Prostate Epithelial Cells and Prostate Human Smooth Muscle Cells.  co-culture	<ul style="list-style-type: none"> <li>• It mimicks prostatic capsule: a core of epithelial secretory cells embedded in a thin layer of smooth muscle cells forming fibromuscular bands</li> <li>• 5-<math>\alpha</math> reductase model: TST conversion in DHA</li> </ul>
<b>CARTILAGE</b>	HCs: Primary Human Chondrocytes	<ul style="list-style-type: none"> <li>• It recapitulates phenotypical features of native cartilage</li> <li>• Metabolic studies: it expresses key biomarkers of tissue differentiation</li> <li>• Cartilage degradation and regeneration</li> <li>• Inflammatory model</li> </ul>
<b>ENDOMETRIUM</b>	T-HESC and HEC-1-A: endometrial fibroblasts and epithelial endometrial cells.  co-culture	<ul style="list-style-type: none"> <li>• Dynamic model to monitor endometrial maturation</li> <li>• Receptivity for embryo implantation</li> <li>• Sexual hormones cycle and metabolism</li> </ul>

Source: VitroScreen, Redeye Research

## Technology

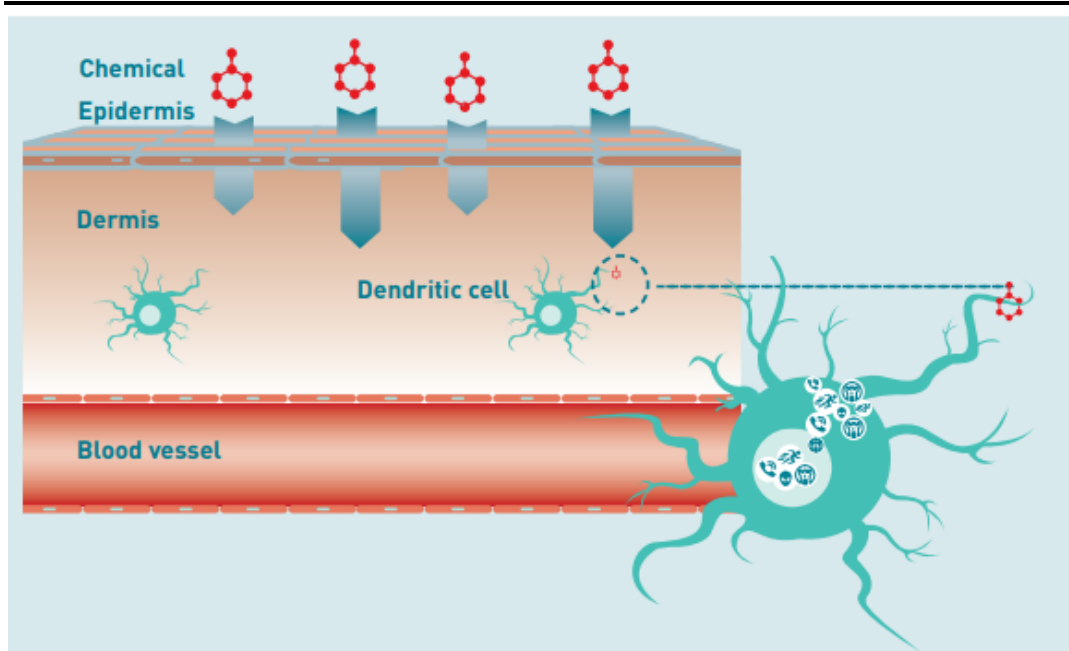
### Sensitization

When an allergy develops, the first step is sensitization to a substance, which occurs if the body considers the substance foreign and comes in contact with our immune system. Proteins and chemicals that are small enough to be absorbed via the skin, respiratory tract, or other means can cause allergies. Sensitization occurs if these are considered foreign, and the body sends out immunological signals and co-stimulation, leading to an allergy, such as contact dermatitis or allergic asthma, if the body is exposed to the substance again.

### Dendritic cells

The immune system's main task is to protect the body from attacks from various types of microorganisms, such as viruses and bacteria. If the immune system considers a substance foreign, the immune system can be activated. Dendritic cells are a type of white blood cell specializing in identifying these foreign substances to start the immune system by producing different kinds of proteins. For example, these cells are in the dermis, the middle of the skin's three layers. When a foreign substance has penetrated the epidermis (the first layer of the skin), the dendritic cells can capture the substance. The dendritic cells then migrate to the lymph nodes, integrating with other white blood cells. These primary t-cells can evolve an immunity against diseases. The recognition of foreign substances activates different mechanics in the dendritic cells and changes the function of the cells. These changes start with the regulation of gene expression of various genes and can be measured using different techniques. This is how the GARD tests differentiate between allergenic chemicals and non-allergenic chemicals. The image below illustrates how a substance (red) is transported to the dendritic cells (green).

### Overview of dendritic cells

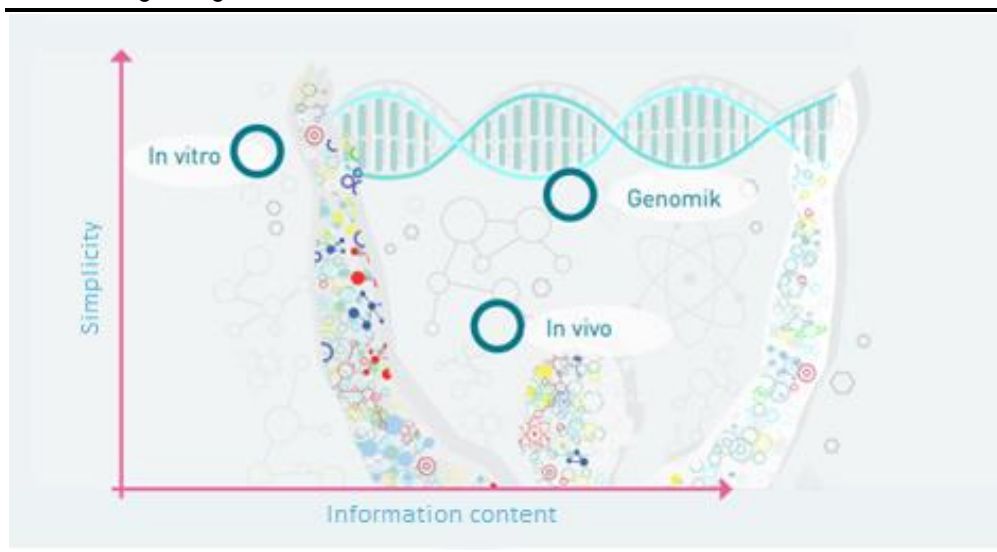


Source: SenzaGen

## Genomics

Genomics, the study of genes, is defined as an organism's entire genetic material and how it functions. Genomics uses DNA (genes) to provide an overview of what happens when, for example, a foreign substance is applied to the skin. Using signals from biomarkers (genes in SenzaGen's case), genomics combines the simple, traditional in-vitro testing with the more complex biological in-vivo testing. Thanks to the some 25,000 genes available for genomic analysis, SenzaGen has created a cell-based in-vitro platform to evaluate a substance's allergic effect. The GARD platform imitates the immune systems, and by examining all these genes, provides a detailed view of what happens when the skin comes into contact with an allergic substance. Modern data processing is required to understand the results. The GARD test is based on a gene structure developed by genomics, statistical analysis, and machine learning.

### The advantages of genomics



Source: SenzaGen

## Machine learning

Machine learning is the study of computer algorithms that can automatically improve using data and experience. It is seen as part of artificial intelligence. Algorithms build a model on sample data called training data or training set. Training the model many times can then be used to analyze new data, also known as the validation set. In SenzaGen's case, the purpose is to recognize gene expression in dendritic cells exposed to allergenic substances. The trained prediction models enable SenzaGen's tests to classify with high accuracy whether a substance is potentially allergenic or non-allergenic.

## Market Overview

Kalorama forecasts the global in-vitro toxicology market to be worth approximately USD 8.9bn in 2023, with a CAGR of 6.8 percent. The market includes several toxicology tests that do not apply to SenzaGen. Still, Kalorama estimates that SenzaGen's targeted segments will be worth USD 1.9bn in 2023, with a CAGR of 8.3 percent given OECD approval in 2022. Following its acquisition of VitroScreen, the potential market has expanded with the increase in targeted segments. Kalorama estimates that the market, including the segments that came with VitroScreen, will be worth USD 3.7bn in 2023, with a CAGR of 7.4 percent. However, SenzaGen only focuses on medical devices in the cytotoxicity segment, and so we judge its total available market at around USD 3bn in 2023.

Global toxicology market (USDm)

Toxicology tests and endpoints	2018	2023	CAGR(%)
Skin irritation, corrosion and sensitization	350	550	9.5
Carcinogenicity	430	650	8.6
Cytotoxicity	950	1 390	7.9
Other toxicity endpoints & tests	600	850	7.2
Genotoxicity	800	1 100	6.6
ADME-Tox	1 700	2 300	6.2
Ocular toxicity	300	400	5.9
Organ toxicity	600	790	5.7
Phototoxicity	220	290	5.7
Dermal toxicity	200	260	5.7
Neurotoxicity	230	300	5.5
<b>Total</b>	<b>6 380</b>	<b>8 880</b>	<b>6.8</b>

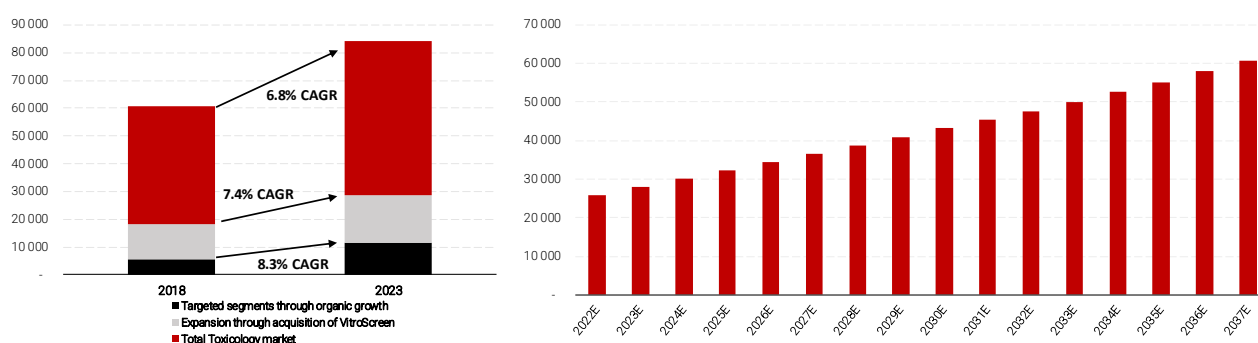
Targeted segments through organic growth  
Expansion through acquisition of VitroScreen

Source: Kalorama and Redeye Research

We believe the total global toxicology market will continue to grow beyond 2023. We assume a value for the total available market of around SEK 25bn in 2022, growing at 7.4 percent per year with a slightly decreasing trend to stabilize at a five percent CAGR from 2032. On these assumptions, the total addressable market value would be close to SEK 48bn in 2032 and SEK 61bn in 2037.

However, this does not include the effect of potential acquisitions that may expand the addressable market in the future. Therefore, the market penetration is challenging to determine in the long-term as SenzaGen has started its acquisition-driven strategy.

Market growth 2018-2023 (left), addressable market growth for 2022-2037 (right)(SEKm)



Source: Kalorama and Redeye Research



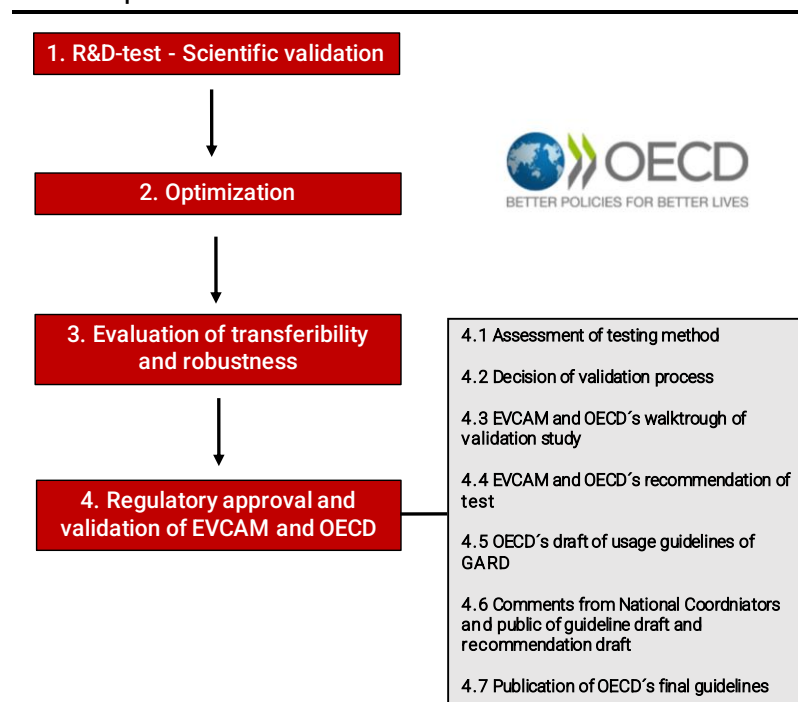
In 2013, the EU banned animal testing in the cosmetics and hygiene industries. An acceleration in developing alternative test methods is ongoing in the US, and many countries outside Europe have already banned animal testing in the cosmetics industry, including Australia, India, and South Korea. As sustainability is a hot topic worldwide, we believe it is only a matter of time before more countries ban animal testing on cosmetics, especially the US, where a few states have already done so. This would increase the demand for SenzaGen's products considerably. We believe regulations regarding animal-free testing in industries such as chemicals are not imminent, but given more alternative testing methods, there is no reason why the rules against animal testing should not also be implemented there in the future. This could open a lot of doors for SenzaGen.

### OECD validation process

The first three steps of the validation process are scientific validation, optimization, and evaluation regarding the transferability of the product. The fourth and final step is the actual approval by the OECD, and this is what SenzaGen is awaiting. The OECD's opinion is planned to be published during 2022, and we see a high likelihood of approval. Comparing GARDskin to other non-animal testing methods that already have OECD approval and taking into account the ESAC's positive opinion last summer, we see no reason why the decision this year should not be favorable for SenzaGen.

Approval would increase SenzaGen's targeted market. The OECD test guidelines apply as validation in all OECD states, and many companies demand OECD validation before buying products. The validation also enables customers to use the test data in product registrations, which will increase the demand for GARDskin. As mentioned earlier, we anticipate approval in our Base Case of SEK 16.

### Validation process



Source: SenzaGen and Redeye Research

### Skin allergies

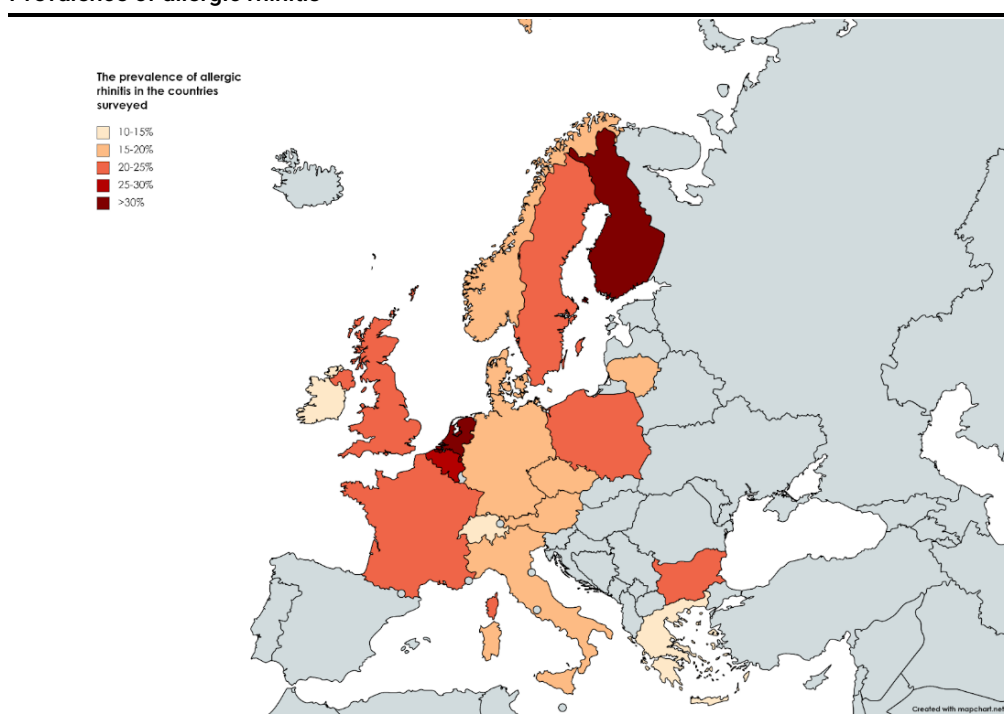
Skin allergies are on the rise, and it is estimated that 20-25 percent of the world's population suffer from one. Allergic contact dermatitis is a common type of skin allergy, whereby people who have had eczema since childhood may be more likely to develop the disorder. It occurs when the immune system responds to a foreign allergen, prompting rashes when a chemical substance irritates the skin's outer layers. Common sources of allergens include nickel and other metals, and personal care products such as shampoos, deodorants, cosmetics, plastic, and glues. Testing the health impact of substances in cosmetic products, cleaning products, and chemicals can allow them to be replaced by safer products. This is where SenzaGen comes in with its GARD platform.

### Respiratory allergies

There are 2.5x more inhaled products from pharmaceutical companies than products applied to the skin. Although no industries currently legally require respiratory sensitization testing, there is a high chance of this in the future. SenzaGen's respiratory sensitization testing method has excellent long-term potential, even if it may not be its primary product right now.

Allergies are increasing dramatically worldwide, and respiratory allergies are the most common form in Europe and worldwide. Allergic rhinitis, caused by an allergic reaction to an allergen, affects 10-30 percent of the world's population, of whom 15-20 percent suffer from a severe form. Allergic asthma is estimated to affect 5-12 percent of the people in Europe and is a form of asthma caused by the bronchial mucosa's exposure to an inhaled airborne allergen.

### Prevalence of allergic rhinitis



Direct costs for respiratory allergy reach millions of euros every year. For example, according to statistics published in 2000 in Germany, costs for allergic rhinitis were EUR 220m, of which EUR 179m was for medication and EUR 41m for doctor and hospital visits (Statistisches Bundesamt, 2000).

## Competitors

### Direct Peptide Reactivity Assay (DPRA)

DPRA is an in-vitro test validated by the OECD and EURL ECVAM to evaluate the reactivity of a chemical compound by using two amino acids, lysine and cysteine. A mixture of the test substance and the amino acid is incubated for 24 hours. The concentration of unbound amino acid is then measured with liquid chromatography, and this is used to evaluate if the test substance should be classified as sensitizing or non-sensitizing. One difference between DPRA and GARDskin is the usage of biomarkers, which are measurable indicators. DPRA uses only one biomarker during testing, whereas GARDskin uses more than 200. Another difference is that DPRA is cell-free while GARDskin uses human cells. The validation study showed that the DPRA testing method is transferable to suitably equipped laboratories with experience in these methods, and that the accuracy of finding sensitizers was 82 percent, which is lower than GARDskin.

### Human Cell Line Activation Test (h-CLAT)

h-CLAT is an in-vitro test validated by the OECD and EURL-ECVAM. The test uses myeloid THP-1 cells, processed with eight different test substance concentrations in 24 hours. After this, the test substance is evaluated by flow cytometry to see if it is allergenic or not. As with the GARD test, h-CLAT also uses human cells, but h-CLAT only uses one to two biomarkers. The validation study showed the accuracy of h-CLAT to be in the region of 76 percent.

### ARE-Nrf2 Luciferase Test Method (KeratinoSens)

Like DPRA and h-CLAT, KeratinoSens is an in-vitro test validated by the OECD and EURL ECVAM. The test uses a cell line of keratinocytes found in the human skin. The cells are then exposed to 12 different concentrations of the test substance for 48 hours to evaluate if the test substance is allergenic using a reporter gene system biomarker. KeratinoSens uses one biomarker. The Givaudan-co-ordinated validation study generated preliminary information on the test method's predictive capacity, finding the accuracy of the KeratinoSens to discriminate skin sensitizers from non-sensitizers to be 90 percent. On another set of chemicals, tested in-house by Givaudan, the accuracy was 75 percent.

### Local Lymph Node Assay (LLNA)

The leading animal test for skin sensitization is the local lymph node assay (LLNA) used on mice. The purpose of the test is to evaluate the skin-sensitizing ability of chemicals and use it as an alternative to traditional tests on guinea pigs, with better conditions for the animals. LLNA has long been a standard test for skin sensitizing and has shown 70-75 percent accuracy in several studies. In 2009, animal testing for cosmetics was banned under EU law, and in 2013 a ban on all animal testing came into force, although with a few loopholes. Under REACH, the EU's chemicals regulation, the safety certification of certain cosmetics ingredients still requires that chemical companies use animal testing. Moreover, our research suggests that animal testing is much more time-consuming and expensive than other methods.

Overall, we judge that SenzaGen's products have an advantage over its competitors. SenzaGen's tests provide more detailed test results due to the number of biomarkers and machine learning. LLNA is still a popular testing method as many industries require it in the product development and registration process. However, we believe that SenzaGen's product portfolio has the potential to be a good alternative for customers that demand a more sustainable option, even if that requires future bans on animal testing.

## Scientific References

Many studies have evaluated GARDskin and its performance in classifying substances as sensitizers or not over the years.

In 2014, Johansson et al. (2014) studied this using a predictive model with a support vector machine to test the classification of 26 blinded chemicals and 11 non-blinded. The results showed an accuracy of 89 percent, sensitivity of 89 percent, and specificity of 88 percent.

### GARDskin study results

	Test set 1	Test set 2	Test set 3	Blinded samples	Combined data
<i>Number of correctly classified sensitizers</i>	7/7	6/7	10/11	16/18	23/25
<i>Sensitivity (%)</i>	100	86	91	89	92
<i>Number of correctly classified nonsensitizers</i>	4/4	3/3	4/5	7/8	11/12
<i>Specificity (%)</i>	100	100	80	88	92
<i>Number of correctly classified compounds</i>	11/11	9/10	14/16	23/26	34/37
<i>Accuracy (%)</i>	100	90	88	89	92

Source: Johansson et al. (2014), Redeye Research

Three years later, Johansson et al. (2017) presented the results from a study by Cosmetic Europe that comparatively evaluated different animal-free techniques using a coherent and blinded test panel of reference chemicals with human and LLNA data. The results showed that GARD is a highly functional assay with a predictive performance of 83 percent in Cosmetic Europe's data set. They also indicated that the average accumulated predictive accuracy of GARD across independent datasets was 86 percent for skin-sensitization hazards.

The same year, another study used the GARD platform to predict three sensitizer potency classes according to the European Classification, Labelling, and Packaging (CLP). The different classes were 1A (strong), 1B (weak), and non-sensitizer. Using a random forest approach, the results showed an overall accuracy of 78 percent when predicting an independent test set consisting of 18 chemicals, six from each class (Zeller et al., 2017).

In 2018, Roberts (2018) compared the GARD test with three other alternatives to animal testing, singly and in combination. The three alternatives are the direct peptide reactivity assay (DPRA), the ARE-Nrf2 luciferase test method, and the human cell line activation test (h-CLAT). These are validated and included in OECD test guidelines. The results showed that GARD outperformed the three alternative methods alone and when the other alternatives are combined as a two out of three strategy on sensitivity, specificity, and accuracy. Based on the results, GARD showed a sensitivity of 90-93 percent, specificity of 79-84 percent, and accuracy of 88-89 percent, indicating that GARD is better than or equal to already validated competitors.

### Comparison of GARD and competitors

Performance index (%)	GARD, 94 cpds in DS2	GARD, 129 cpds in DS1	DPRA + h-CLAT in DS2	2 out of 3 (DPRA, ARE-Nrf2, h-CLAT) in DS2
<i>Sensitivity</i>	90	93	97	86(82)
<i>Specificity</i>	84	79	52	76(72)
<i>Accuracy</i>	88	89	86	83(79)
<i>PPV</i>	94	91	86	89
<i>NPV</i>	75	84	84	69

Source: Roberts (2018), Redeye Research

In 2019, Johansson et al. (2019) perform an inter-laboratory ring trial of GARDskin, conducted in compliance with OECD guidance documents and comprising a blinded chemical test set of 28 chemicals. The result show an inter-laboratory reproducibility of 92.0%, a within-laboratory reproducibility ranged between 82.1-88.9% and a cumulative predictive accuracy across the three laboratories of 93.8%. The study concludes that GARDskin is a robust and reliable method for the identification of skin sensitizing chemicals and suitable for stand-alone use or as a constituent of integrated testing.

#### GARDskin evidence

True Group	SenzaGen		Eurofins		BRT		Cumulative	
	(19 + 9)		(19 + 8)		(17 + 8)		(55 + 25)	
	S	NS	S	NS	S	NS	S	NS
<b>S</b>	17	2	18	1	16	1	51	4
<b>NS</b>	1	8	0	8	0	8	1	24
<b>Accuracy (%)</b>	89.3		96.3		96.0		93.8	
<b>Sensitivity (%)</b>	89.5		94.7		94.1		92.7	
<b>Specificity (%)</b>	88.9		100.0		100.0		96.0	

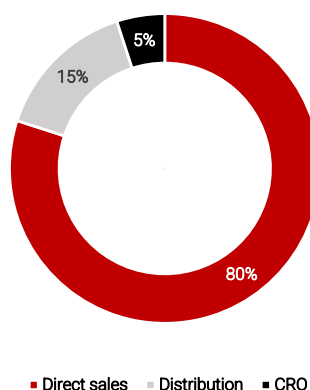
Source: Johansson et al. (2019), Redeye Research

In a study by Johansson et al. (2020), the authors presented results regarding GARDpotency in predicting skin sensitizer potency. The performance was validated in a blinded ring trial according to OECD guidance documents. The results showed an estimated cumulative accuracy of 88 percent across three laboratories and nine independent experiments. The in-laboratory reproducibility measures ranged between 62.5 and 88.9 percent, and the between-laboratory reproducibility was estimated at 61.1 percent. The authors concluded that the in-vitro GARDpotency assay constitutes a step toward non-animal testing alternatives for skin sensitizers.

## Business Model

In previous years, SenzaGen's business strategy was built on direct sales from its Lund headquarters and sales through CROs, with other companies worldwide using its products. In recent years, it has changed strategy, decreasing the CRO proportion of the business and mainly focusing on direct sales and via distributors (testing still performed at the laboratory at its headquarters).

### Current sales split



Source: SenzaGen, Redeye Research

The company's strategy focuses on both organic and acquisition-driven growth. Organic growth comes from maintaining the current customer base and capturing new customers with a sales and marketing approach. We judge that focusing on capturing large companies in the targeted sectors is a good strategy thanks to the possibility of larger orders and of a ripple effect (large customers and orders working as marketing), attracting new customers. We also see the flexibility in the business as positive both at this stage and in the future, with a flexible study design creating higher demand for SenzaGen's products.

Acquisition-driven growth comes from acquiring companies with products that can expand SenzaGen's offering to meet new endpoints. It has only made one acquisition so far, but SenzaGen's strategy is to acquire growing and profitable companies, like VitroScreen, with the demand to operate in non-animal testing methods. This strategy also focuses on realizing synergies between group companies, enabling cross-sales through a joint sales force, and allocating tests to specific labs. The size of the companies may vary in the future, but we estimate sales up to SEK 75m.

### Acquisition-driven growth strategy

Targeting category leadership	Realize synergies between Group companies	Rapid sales growth
<ul style="list-style-type: none"> <li>Targeting acquisitions of growing and profitable companies</li> <li>Complementary acquisitions along the value chain</li> <li>Expanding SenzaGen's offering to meet new end-points</li> </ul>	<ul style="list-style-type: none"> <li>Cross-sales with joint sales forces</li> <li>Expanded test sales</li> <li>Allocate tests to specific labs</li> </ul>	<ul style="list-style-type: none"> <li>Acquisition of new knowledge and technologies</li> <li>Sales organization &amp; customer list</li> <li>Commercially operating labs</li> </ul>

Source: SenzaGen, Redeye Research

Currently, SenzaGen has a customer base with large companies in its targeted industries. Examples include Essity, a leading global hygiene and health company; Galderma, an international pharmaceutical company that develops and markets products in medical skincare; and Research Institute for Fragrance Materials (RIFM), which gathers and analyzes scientific data to encourage uniform safety standards related to the use of fragrance ingredients.

#### Selected Customers



Source: SenzaGen, Redeye Research

#### Direct sales

Approximately 80 percent of the company's sales are direct to its laboratory in Lund, Sweden. The price of testing a substance is SEK 50,000. An average order is around two to three substances, while large orders are up to 10-20 substances where both have a gross margin of approximately 65-70 percent. SenzaGen says that orders are split 50:50 between new and recurring customers. Recurring customers typically want to test a substance related to product development rather than new products frequently, and so it is essential for SenzaGen to focus also on increasing its customer base. We believe this is crucial at this stage for the company.

We estimate that the laboratory in Lund can perform up to 1,500-2,000 tests per year depending on the sizes of the orders, meaning the capacity to perform tests worth up to SEK 100m. Adding new capacity is a matter of expanding standard laboratory space, equipment, and personnel which is not complex or very costly.

#### Distribution

The distribution part of the company works as the middle man between SenzaGen and its customers. Its distributors have the customer contact and order the tests to be performed at the Lund laboratory. We assume that the price per test has a 15-20 percent discount to direct sales with the same COGS as direct sales, implying a gross margin of around 55 percent. Currently, distribution sales represent approximately 15 percent of total sales, and we expect this to remain largely the same.

#### CROs

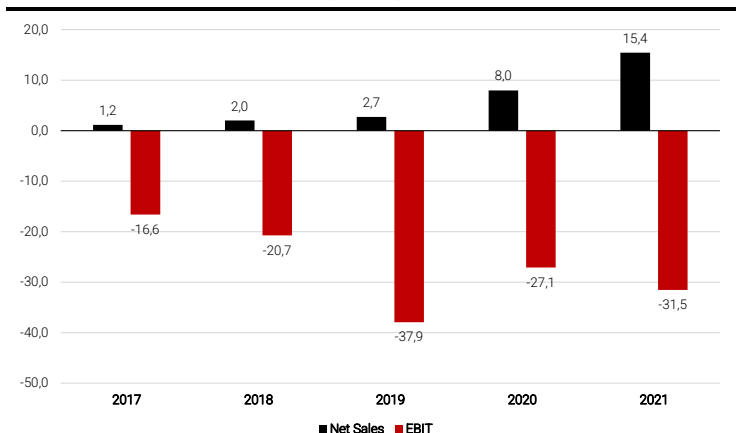
Currently, SenzaGen has three CROs: two in the US and one in Germany. Its US subsidiary helps the CROs and also handles marketing of the testing methods to potential new customers. The tests in the CRO part are not performed in Lund; instead, the CROs buy a license for each substance tested to use SenzaGen's testing methods. The license price is SEK 15,000, and the gross margin is close to 100 percent. Currently, only five percent of sales are via CROs, but this could increase in the future when the Lund laboratory proves too small. Having CROs is also crucial in getting validation by the OECD, as one criterion is that the testing method should be transferable with the same accuracy.

## Financials

Currently, SenzaGen is in an early phase and is not yet profitable. In 2015-2019, the company had sales of around SEK 1-3m but these have recently increased with the expanding customer base, which we see as the start of the next step toward a break-even year in 2025. The lower EBIT in 2021 versus 2020 was the result of expenses related to the acquisition of VitroScreen and costs associated with the change of CEO in the second half of 2021.

The 28<sup>th</sup> of April, 2022, SenzaGen published an update of the sales performance during the first quarter of 2022. The net sales totaled SEK 9.0m, where SEK 4.2m came from organic sales and SEK 4.8m from VitroScreen. This represented 118% YoY organic growth and 373% YoY total growth. The strong sales update indicates that SenzaGen is moving in the right direction and that we can have high expectations for the year in general, especially because of increased demand with a potential OECD validation.

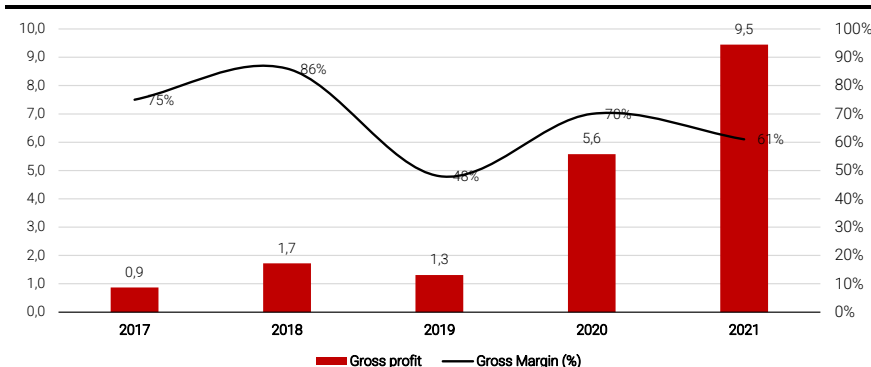
**Sales and EBIT in 2017-2021 (SEKm)**



Source: Redeye Research

The gross profit has ramped up with the sales over the past couple of years. The gross margin has changed significantly over the past five years but was 60-70 percent in 2020 and 2021. We expect the gross margin to stay in this region for the future, with a slight rise in the long term. As orders become larger, we believe testing will become more efficient, resulting in a lower COGS per test. In the long term, we also believe the CRO part of the company will increase, resulting in a higher gross margin since the cost of a CRO order is close to zero.

**Gross profit and gross margin in 2017-2021 (SEKm)**

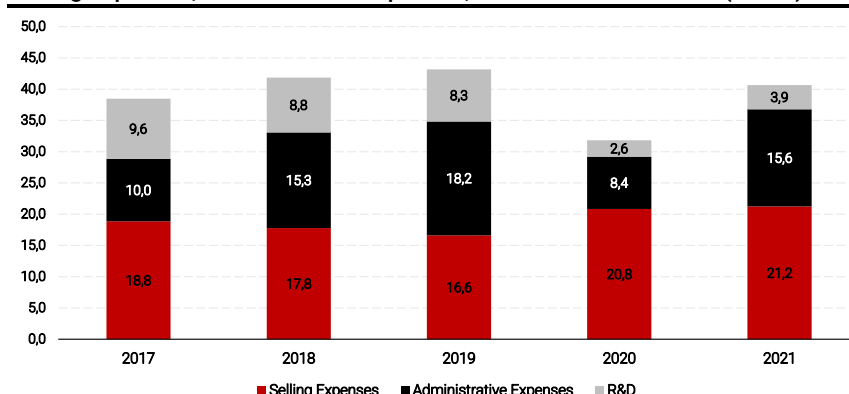


Source: Redeye Research



Over the past five years, selling expenses have been stable at around SEK 20m, although we expect them to increase slightly with the higher sales in the coming years. R&D expenses have decreased in the past two years versus 2017-2019, when there was a higher focus on developing new products.

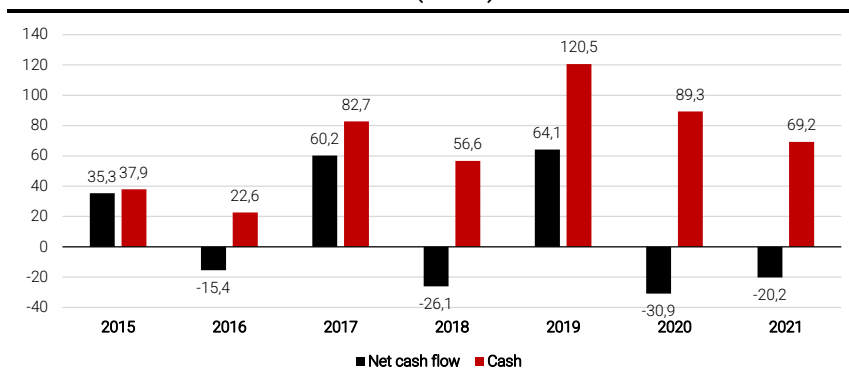
#### Selling expenses, administrative expenses, and R&D in 2017-2021 (SEKm)



Source: Redeye Research

Last year, SenzaGen conducted a directed share issue, raising SEK 30m in October to finance the acquisition of VitroScreen. We expect the current cash position of SEK 69m to last until the first break-even year, which we expect to be 2025. We consider this achievable, but we note that any future issues are likely to be in connection with potential acquisitions.

#### Cash and net cash flow in 2015-2021 (SEKm)



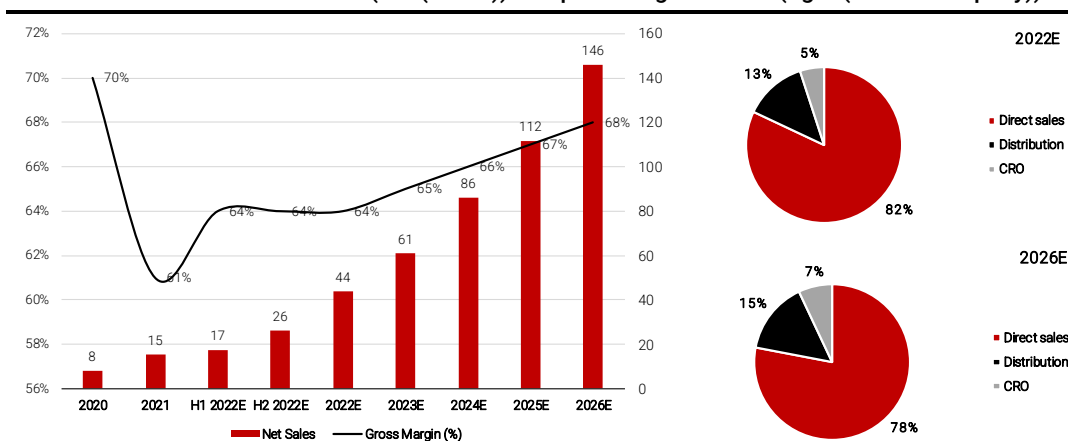
Source: Redeye Research

## Forecasts

The company has shown significant sales growth of 192 percent and 94 percent for 2020 and 2021, respectively. Sales are still relatively low, but we argue that this is only the beginning of significantly higher sales. In 2021, the company reported sales of approximately SEK 15m, of which SEK 3.3m was from VitroScreen (only included in November and December).

We assume a price of SEK 50,000 per test, with a gross margin of 63 percent for direct sales, 54 percent for distribution sales, and 100 percent for sales via CROs. Currently, direct sales account for around 80 percent of total sales, but we expect this will decrease somewhat in the long term, with the percentage of CROs coming up.

### Sales estimates for 2022E-2026E (left (SEKm)) and percentage of sales (right (Parent company))



Source: Redeye Research

### Income statement forecasts for 2020-2025E

	2020	2021	H1 2022E	H2 2022E	2022E	2023E	2024E	2025E
Net sales	8	15	17	26	44	61	86	112
Gross margin	70%	61%	64%	64%	64%	65%	66%	67%
Sales growth	192%	94%	-	-	183%	40%	41%	30%
Selling expenses	-21	-21	-9	-13	-22	-24	-27	-31
Administrative expenses	-8	-16	-9	-10	-19	-21	-24	-27
R&D	-3	-4	-3	-3	-6	-7	-7	-7
EBITDA	-27	-32	-10	-9	-19	-12	-1	10
EBITDA margin	-341%	-204%	-57%	-34%	-43%	-20%	-1%	9%
Depreciation	-	-	1	1	2	2	3	3
Amortization	-	-	2	2	3	4	4	4
EBIT	-27	-32	-13	-12	-24	-18	-7	4
EBIT margin	-341%	-204%	-71%	-44%	-55%	-29%	-8%	3%
Interest expenses/income	0	0	-	-	-	-	-	-
EBT	-27	-31	-13	-12	-24	-18	-7	4
Net Income	-27	-31	-13	-12	-24	-18	-7	4

Source: Redeye Research

### Net sales and gross margin

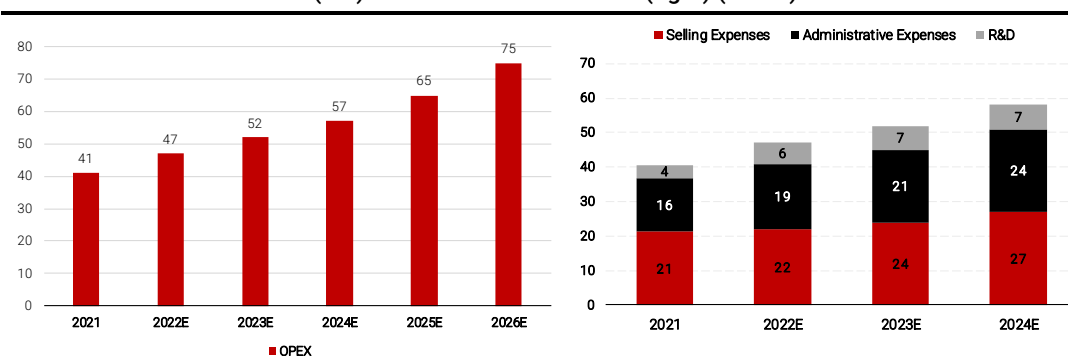
We estimate total sales of close to SEK 112m in 2025E, with a CAGR of 64% for 2022E-2025E. In our Base Case of SEK 16, we assume OECD approval in the middle of 2022, bolstering sales in the second half of the year. We also expect a higher gross margin in the future as the customer base is likely to include larger companies, resulting in more sizable orders. A large order does not have significantly different time or laboratory space requirements versus a smaller order, which is one of the reasons why a higher gross margin is reasonable. Another reason is that, as mentioned before, the CRO part of the

company may grow in the future, elevating the total gross margin. Note that we do not assume any acquisitions in these estimates. SenzaGen has only acquired one company so far. Even if we expect more acquisitions in the future, it is too challenging to determine the size of acquired companies and even more so how often they will take place.

### OPEX assumptions

The acquisition of VitroScreen will push up OPEX versus 2021, and we believe there will be a need for future additional costs to ramp up the sales and continue growing the business. However, we forecast sales growing faster than costs during our forecast period. As mentioned above, selling expenses have not increased at the same rate as sales. We believe this will be the case in the next few years as well, with a relatively small increase. However, staff numbers will increase as the company expands its business, leading to higher administrative expenses in the coming years. We expect a rise in R&D costs owing to the acquisition of VitroScreen and SenzaGen's ongoing new product development.

### Total OPEX for 2021-2026E (left) and 2021-2024E in detail (right) (SEKm)

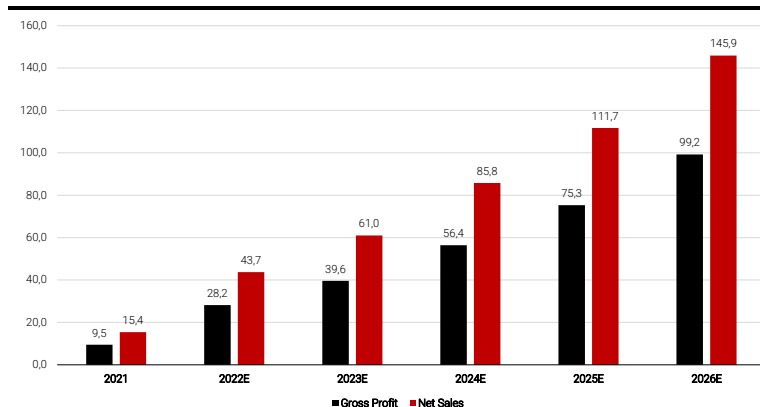


Source: Redeye Research

### The road to break-even

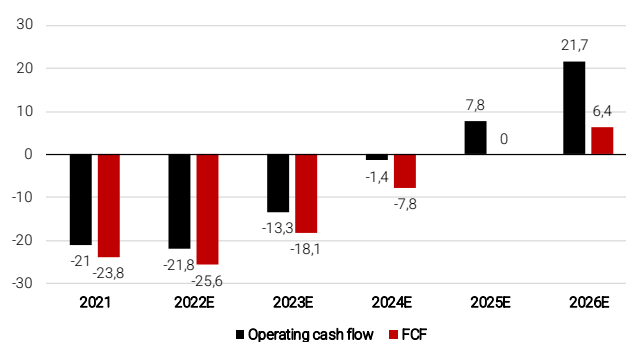
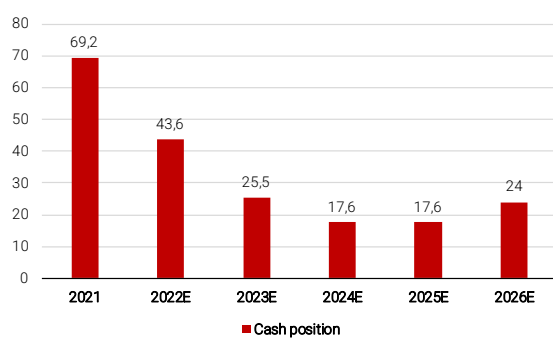
We believe that EBIT will be positive in 2025, with the validation of GARDskin during 2022 as a major factor in future sales. This is a reasonable assumption, we argue, unless the company makes acquisitions, in which case the first profitable year could be earlier than our estimates expect. We also anticipate validation processes for the other testing methods in SenzaGen's product portfolio in the long term. These would simplify its ability to expand the business in the future and to continue increasing sales. Thanks to its current solid cash position of SEK 69m, we expect SenzaGen has cash enough until the first break-even year in 2025. Based on our sales forecasts, we expect SenzaGen to improve its cash flow during the forecasting period, and we judge the company will be cash-flow-positive in 2025 and thereafter.

## Sales and Gross profit for 2021-2026E



Source: Redeye Research

## Cash position 2021-2026E (left), and cash flow 2021-2026E (right)(SEKm)



Source: Redeye Research

## Valuation

Our valuation of SenzaGen is based on a discounted cash flow model. Our analysis suggest a Base Case of SEK 16, representing 63% upside from the current share price levels. As the OECD validation, expected during 2022, would have a significant effect on future sales, we believe this decision and sales reports will be significant in closing the valuation gap, and we expect SenzaGen to achieve this within the next 12 months.

## Fair Value Range

At Redeye, we use three different scenarios to value a company's stock. These provide a more dynamic view of the case. We apply a 14 percent WACC across all scenarios.

- Base Case: SEK 16 per share (63% upside)
- Bull Case: SEK 27 per share (176% upside)
- Bear Case: SEK 5 per share (49% downside)

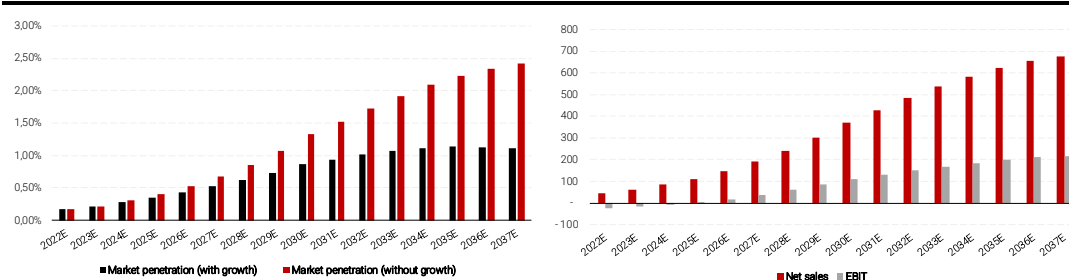
## Base Case: SEK 16

In our SEK 16 Base Case scenario, we assume that the OECD will validate GARDskin in mid-2022. The validation will be a major catalyst in ramping up sales, for which we expect a CAGR of 77% until 2024 and an overall CAGR of 27% across the whole forecast period (until 2037). The EBIT margin will be negative until 2025 and then 32 percent at the end of the forecast period. We also assume terminal growth of two percent.

Valuation summary (SEKm) - Base Case			
DCF value	343	WACC	14%
Net debt	-44	Terminal growth	2%
Equity value	386	Terminal EBIT	32%
Number of shares (m)	24	Tax rate	20,6%
Equity value per share	16	Sales CAGR 2022-2027	52%
		Sales CAGR 2027-2037	13%

Source: Redeye Research

## Net sales for 2022E-2037E (right), and market penetration (left) (SEKm)



Source: Redeye Research

## Bull Case: SEK 27

Our SEK 27 Bull Case scenario assumes an OECD validation on GARDskin during 2022 and that the sales ramp-up is even faster than in our Base Case scenario. We assume a sales CAGR of 88% until 2024 and a break-even year in 2024. We also assume sales to be 20% higher per year than in the Base Case, with sales of SEK 811m in 2037 and an EBIT margin of 37%, with terminal growth of two percent.

- Sales in 2022, 2023, and 2024: SEK 52m, SEK 73m, SEK 103m
- EBIT in 2022, 2023, and 2024: SEK -20m, SEK -11m, SEK 2m

## Bear Case: SEK 5

Our SEK 5 Bear Case assumes negative decision in the OECD validation, which will affect sales growth, and sales overall thus grow more slowly than expected. We estimate that the first profitable year is in 2026 and that sales will be 30 percent lower per year than in our Base Case scenario, with a sales CAGR of 57% until 2024. Sales are SEK 473m in 2037 with an EBIT margin of 22 percent. The terminal year is 2037, with terminal growth of two percent.

- Sales in 2022, 2023, and 2024: SEK 31m, SEK 43m, SEK 60m
- EBIT in 2022, 2023, and 2024: SEK -25m, SEK -19m, SEK -14m

## Sensitivity Analysis

Our valuation is sensitive to changes in terminal growth and WACC. WACC is used when calculating the discounted cash flow and greatly impacts the valuation. Therefore, we provide a sensitivity analysis showing the fair value of our Base Case with changes in these ratios.

**Sensitivity analysis**

		WACC				
		12%	13%	14%	15%	16%
Terminal Growth	1,0%	21	18	16	14	12
	1,5%	21	18	16	14	12
	2,0%	22	19	16	14	12
	2,5%	22	19	16	14	12
	3,0%	23	19	17	14	13

Source: Redeye Research

## Peer Valuation

In addition to our DCF valuation, we offer a peer group analysis that compares SenzaGen to other medtech companies in the Nordic region. These eight companies have a similar enterprise value to SenzaGen and are also in an early commercialization phase. We argue that the best measurement is EV/sales because SenzaGen is not currently profitable.

### Peer valuation

Company	EV(SEKm)	EV/Sales			
		LTM	2022E	2023E	2024E
Acarix AB	150	40.0x	11.5x	4.5x	2.1x
AroCell	121	10.1x	4.3x	3.0x	2.0x
Biovica	740	370x	30.8x	10.0x	4.7x
Dignitana AB	444	7.8x	4.4x	2.5x	N/A
Episurf Medical AB Class B	554	84.0x	46.4x	27.0x	14.6x
IRRAS AB	95	4.2x	2.0x	0.7x	0.4x
NeoDynamics	111	95.5x	3.3x	1.4x	0.9x
SciBase Holding AB	236	20.1x	11.2x	6.4x	N/A
<b>Median</b>	<b>193</b>	<b>30x</b>	<b>7.8x</b>	<b>3.75x</b>	<b>2x</b>
<b>SenzaGen</b>	<b>188</b>	<b>12.2x</b>	<b>4.3x</b>	<b>3.1x</b>	<b>2.2x</b>

Source: Factset and Redeye Research

The eight companies' EV/sales medians for the last 12 months and for 2022E are 30x and 7.8x, respectively. Applying those to SenzaGen's sales in 2021 of SEK 15.4m and estimated 2022 sales of SEK 44m and adding the estimated cash position of SEK 44m, the equity value is SEK 507m using LTM sales and SEK 385m using 2022E. This represents share prices of SEK 21 and SEK 16, respectively, supporting our DCF valuation of SEK 16. We expect the EV/sales multiple to increase in the coming 12 months as the company ramps up its sales and as its long-term potential becomes better recognized by investors.

## Appendix

### People – Board members

#### **Carl Borrebaeck, Chairman of the board**

- Shares: 1,698,571
- At SenzaGen since 2010
- Professor of Immunotechnology, DSc major in molecular immunology, MSc in Chemical Engineering and a MSc in Life Science
- Founder of SenzaGen, Immunovia AB and BioInvent International AB.
- Other current assignments: Dr. Borrebaeck is also chairman of Immunovia AB, PainDrainer AB, CB Ocean Capital AB, and board member of Alligator Bioscience AB and Scandion A/S. In addition, he has won several awards for his entrepreneurship and groundbreaking research, including AkzoNobel's Science prize in 2009, and the Biotech Builder Award in 2017.

#### **Laura Chirica, board director**

- Shares: 0
- At SenzaGen since 2017
- PhD in Biochemistry, MSc in Biochemistry and BSc in Biotechnology
- 20 years of experience from commercial positions in both startups and multinationals from the life science and diagnostics industries. Previous positions include VP Sales and Marketing at Euro Diagnostica AB, director at Purification Technologies Europa Sartorius Stedim, Global Marketing Director at Dako A/S, and Global marketing program manager at GE Healthcare.

#### **Anki Malmberg Hager, board director**

- Shares: 383,000
- At SenzaGen since 2019
- Ph.D. in Immunotechnology, MSc in Chemical Engineering, and a Pharma MBA.
- Anki has extensive experience with smaller life science companies and has been CEO of SenzaGen between 2014 and 2019, CEO of Cantargia AB, Ximmune AB, and Diaprost AB, Investment director at LU Bioscience AB and VP Business Development at Alligator Bioscience AB.
- Other current assignments: CEO of PainDrainer AB, board member of Avena Partners AB, DiaProst AB, PainDrainer AB and Hager Consulting AB.



**Ian Kimber, board director**

- Shares: 1,500
- At SenzaGen since 2015
- PhD in Immunotechnology, MSc in Chemical Engineering, and a Pharma MBA.
- Mr Kimber serves as Emeritus Professor of Toxicology at the University of Manchester. He has extensive experience from academia, the pharmaceutical, biopharmaceutical, and agrochemical industries. Ian has also won several awards for his distinguished scientific work and received the OBE in the Queen's Birthday Honours list in 2011.

**Paul Yianni, board director**

- Shares: 20,000
- At SenzaGen since 2020
- PhD in Chemistry
- Over 30 years of management experience from the chemicals industry, and has a broad international experience from various technical and commercial functions, including at Dow Corning and Shell Chemicals. His previous positions include DEO of Spolchemie in Czechia and Head of M&A at DIC Europe in Germany.

**Paula Zeilon, board director**

- Shares: 6,000 and 10,000 Warrants
- At SenzaGen since 2020
- MSc Chemical engineering and Business Administration
- 30 years of experience in the life science industry. Her past positions include CEO of Life Science Foresight Institute, CEO of Alligator Biosciences AB, Director of marketing at Dako A/S, Director of marketing at Biotage AB, and management positions with Pharmacia Biotech (now Cytiva)

## People – Executive Management

### **Peter Nählstedt, CEO**

- Shares: 23,919 and 25,000 Warrants
- At SenzaGen since 2018, CEO since 2021
- MSc in Chemical Engineering and a BSc in Business Administration
- Mr Nählstedt appointed to SenzaGen's board in 2018 after several years in the industry including management positions with Trelleborg Marine Systems, GE Healthcare, and CEO at Probi AB.

### **Marianne Ohlsson, Chief Financial Officer**

- Shares: 114,285 and 50,000 Warrants
- At SenzaGen since 2016
- Certified financial manager via FAR
- 25 years of experience from Lund University where she worked as a department economist and most recently as administrative manager at the Department of Immunotechnology. Marianne has also been a board member at the Faculty of Engineering LTH at Lund University and the department of immunotechnology.

### **Anna Chérouvrier Hansson , VP Sales & Business Development**

- Shares: 19,153 and 65,00 Warrants
- At SenzaGen since 2017
- MSc in European Business Administration and Business Law and a BSc in Business Administration
- Experience in marketing, sales, and business development from Camurus, Novo Nordisk, Gambro, and DuPont among others. In addition, Anna has been partner at Zitha consulting and head of life science investments at Invest in Skåne.

### **Tina Dackemark Lawesson, VP Marketing, and Communications**

- Shares: 1,000 and 65,000 Warrants
- At SenzaGen since 2018
- BSc of education (languages) as well as studies in journalism
- Experience in marketing, IF and communication at life science and technology companies that were in build up and growth phase. She has also have similar positions at INVISIO, Cellavision and Enzymatica

### **Henrik Johansson, Chief Scientist**

- Shares: 526 and 10,000 Warrants
- At SenzaGen since 2014
- MSc in Biotechnology Engineering and Ph.D. in Immunotechnology
- More than 10 years of experience in research and development within the fields of cell and molecular biology. He is specialized in vitro assays for predictive immunotoxicology and co-developer of the GARD technology platform.

**Åsa Nyhlén, VP Operations**

- Shares: 6,300 and 50,000 Warrants
- At SenzaGen since 2021
- MSc in molecular biology
- 20 years of experience being responsible for laboratory services in the pharmaceuticals, medical devices and food industries. This includes management positions with Novo Nordisk, Dako and BioGaia.

**Helen Olsson, VP HR**

- Shares: 5,000
- At SenzaGen since 2020
- Degree in behavioral science
- Over 20 years of experience in organization development, change management, and both operational and strategic HR, including as VP HR at BioGaia.

## Summary Redeye Rating

The rating consists of three valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 1 points. The maximum score for a valuation key is 5 points.

### Rating changes in the report

**People: 3**

The management is solid and bring extensive experience from commercial and growth companies, and M&A. In addition, there is strong sector expertise. The board brings long experience in life science, growth companies, and M&A. It is also positive that one of the founders, Carl Borrebaeck, is still involved in the company as the chairman.

**Business: 3**

The business model is appealing, with a solid strategy to become profitable in the future. Around half of the revenues come from existing customers, and the targeted market will expand in the future as sustainability remains a hot topic around the globe. SenzaGen has built an attractive strategy focusing on both long-term organic and acquisition-driven growth.

**Financials: 1**

SenzaGen is currently in the early stages and has a few years ahead of it before it turns profitable. However, we have seen a tendency of sales starting to ramp up and estimate that the company will become profitable in 2025.

	2021	2022E	2023E	2024E	DCF Valuation Metrics		Sum FCF (SEKm)		
INCOME STATEMENT					Initial Period (-)		189		
Net sales	15	44	61	86	Stable Period (2037-)		154		
Cost of Revenues	6	16	21	29	Firm Value		343		
Gross Profit	9	28	40	56	Net Debt		-44		
Operating Expenses	41	47	52	57	Equity Value		386		
EBITDA	-32	-19	-12	-1	Fair Value per Share		16		
Depreciation & Amortization	0	5	5	6					
EBIT	-32	-24	-18	-7					
Net Financial Items	0	0	0	0		2021	2022E	2023E	2024E
EBT	-31	-24	-18	-7	CAPITAL STRUCTURE				
Income Tax Expenses	0	0	0	0	Equity Ratio	0,8	0,8	0,7	0,6
Non-Controlling Interest	0	0	0	0	Debt to equity	0,0	0,0	0,0	0,0
Net Income	-31	-24	-18	-7	Net Debt	-69	-44	-25	-18
					Capital Employed	110	86	68	61
					Working Capital Turnover	-1,4	-5,2	-8,2	-13,0
BALANCE SHEET									
Assets									
Current assets					GROWTH				
Cash & Equivalents	69	44	25	18	Revenue Growth	94%	183%	40%	41%
Inventories	3	4	6	9					
Accounts Receivable	9	10	14	20					
Other Current Assets	0	0	0	0					
Total Current Assets	81	58	46	46	PROFITABILITY				
Non-current assets					ROE	-29%	-25%	-23%	-11%
Property, Plant & Equipment, Net	3	2	2	2	ROCE	-29%	-28%	-26%	-11%
Goodwill	13	13	13	13	ROIC	-106%	-58%	-42%	-16%
Intangible Assets	36	35	35	35	EBITDA Margin (%)	-204%	-43%	-20%	-1%
Right-of-Use Assets	0	0	0	0	EBIT Margin (%)	-204%	-55%	-29%	-8%
Shares in Associates	0	0	0	0	Net Income Margin (%)	-203%	-55%	-29%	-8%
Other Long-Term Assets	0	0	0	0					
Total Non-Current Assets	52	51	50	50	VALUATION				
Total Assets					Basic EPS	-1,3	-1,0	-0,7	-0,3
					Adjusted Basic EPS	-1,3	-1,0	-0,7	-0,3
Liabilities					P/E	neg	neg	neg	neg
Current liabilities					EV/Revenue	12,2	4,3	3,1	2,2
Short-Term Debt	0	0	0	0	EV/EBITDA	neg	neg	neg	neg
Short-Term Lease Liabilities	0	0	0	0	EV/EBIT	neg	neg	neg	neg
Accounts Payable	3	7	9	13	P/B	35,8	35,7	45,0	50,1
Other Current Liabilities	20	16	18	22					
Total Current Liabilities	24	23	28	35	SHAREHOLDER STRUCTURE		CAPITALVOTES %		
Non-current liabilities					Carl Borrebaeck			7.02%	7.02%
Long-Term Debt	0	0	0	0	Malin Lindstedt			6.71%	6.71%
Long-Term Lease Liabilities	0	0	0	0	Suad Nimani			3.97%	3.97%
Other Long-Term Liabilities	0	0	0	0	Nordnet Pensionsförsäkring			3.77%	3.77%
Total Non-current Liabilities	0	0	0	0	Futur Pension			3.06%	3.06%
Non-Controlling Interest					SHARE INFORMATION				
Shareholder's Equity	110	86	68	61	Reuters code				SENZA.ST
Total Liabilities & Equity	134	109	96	96	List				First North
CASH FLOW					Share price				9.8
NOPAT	-32	-24	-18	-7	Total shares, million				24.1
Change in Working Capital	12	-3	-1	-1	MANAGEMENT & BOARD				
Operating Cash Flow	-21	-22	-13	-1	CEO				Peter Nählstedt
Capital Expenditures	0	-1	-2	-3	CFO				Marianne Ohlsson
Investment in Intangible Assets	-2	-2	-3	-4	Chairman				Carl Borrebaeck
Investing Cash Flow	-27	-4	-5	-6	ANALYSTS				
Financing Cash Flow	27	0	0	0	Gustaf Meyer				Redeye AB
Free Cash Flow	-24	-26	-18	-8	Oscar Beraman				Mäster Samuelsgatan 42, 10tr
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## Redeye Rating and Background Definitions

### Company Quality

Company Quality is based on a set of quality checks across three categories; PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

### People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

### Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

### Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

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## Disclaimer

### Important information

Redeye AB ("Redeye" or "the Company") is a specialist financial advisory boutique that focuses on small and mid-cap growth companies in the Nordic region. We focus on the technology and life science sectors. We provide services within Corporate Broking, Corporate Finance, equity research and investor relations. Our strengths are our award-winning research department, experienced advisers, a unique investor network, and the powerful distribution channel redeye.se. Redeye was founded in 1999 and since 2007 has been subject to the supervision of the Swedish Financial Supervisory Authority.

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Redeye does not issue any investment recommendations for fundamental analysis. However, Redeye has developed a proprietary analysis and rating model, Redeye Rating, in which each company is analyzed and evaluated. This analysis aims to provide an independent assessment of the company in question, its opportunities, risks, etc. The purpose is to provide an objective and professional set of data for owners and investors to use in their decision-making.

### Redeye Rating (2022-05-05)

Rating	People	Business	Financials
5p	32	15	4
3p - 4p	155	137	48
0p - 2p	5	40	140
Company N	192	192	192

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### CONFLICT OF INTERESTS

Gustaf Meyer owns shares in the company : No

Oscar Bergman owns shares in the company : No

Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.