

Breakthrough for SenzaGen in both sales and technology



We closed our breakthrough year, 2022, on a very strong note with a 110% increase in sales for the second half year to SEK 21.8 million. Organic sales accounted for SEK 12.1 million, representing 70% organic growth. Late in the year, we saw strong demand for GARD® tests, which was largely driven by the OECD approval received earlier in the year. For the full year, total sales increased by as much as 171% to SEK 41.8 million. With our OECD-approved test, new innovative tests and a broader offering in a market that is continuing to grow from technological, regulatory and ethical drivers, I can see us in a very favorable position for continued high growth.”

Peter Nählstedt, President and CEO



Full year 1 January–31 December

- » Net sales totaled SEK 41.8 (15.4) million.
- » EBITDA amounted to SEK -15.7 (-27.3) million.
- » Earnings per share were SEK -1.03 (-1.35).
- » Cash and cash equivalents at 31 December amounted to SEK 40.0 (69.2) million.
- » The board proposes that no dividend be paid to the Company's shareholders.

Second half year 1 July–31 December

- » Net sales totaled SEK 21.8 (10.4) million.
- » EBITDA amounted to SEK -6,6 (-15.5) million.
- » Earnings per share were SEK -0.47 (-0.78).

Significant events during the second half year

- » SenzaGen completed its largest test order to date for GARD®skin from a new customer, a world leader in chemicals, for a cumulative value of approximately SEK 1 million.
- » SenzaGen acquired ToxHub, an Italian company offering toxicology advisory services with specific expertise in medical devices and pharmacology.

Message from the CEO

We closed our breakout year, 2022, on a very strong note with a 110% increase in total sales for the second half year to SEK 21.8 million. Organic sales accounted for SEK 12.1 million, representing 70% organic growth.

In the latter part of the year, we saw strong demand for GARD® tests, which was largely driven by the OECD approval received earlier in the year. At the same time, the US pharmaceuticals industry took a key step away from animal testing with the passage of the FDA Modernization Act, making animal testing no longer mandatory. We estimate that this change will further increase demand for non-animal tests, creating an even more favorable market position for GARD® and the Group's other innovative tests.

Strong 2022 performance

2022 was the year SenzaGen achieved a breakthrough both in sales and with its technology. Our sales increased during the year by as much as 171%, driven by very strong organic growth of 77%, and sales from our two profitable acquisitions. This strong growth combined with effective cost controls enabled us to cut our loss by more than half in the second half of the year compared to the corresponding period last year, and we are now rapidly approaching breakeven.

The drivers of our success in delivering such strong organic growth are our commercial team but also the technology portfolio that the Company continues to develop. One record-high order after another came in for the GARD® platform during the year. We received our largest order ever, worth over SEK 4 million, for our most recently developed test, GARD®skin Dose-Response. Additionally, in the second half year, we received our largest order to date for GARD®skin from a new customer, a world leader in chemicals, for a cumulative value of approximately SEK 1 million.

The OECD approval

GARD®skin became our first test to be approved as an OECD Test Guideline. Coming in the middle of the year, this approval is a key milestone and a major breakthrough for our technology as the first validated genomics-based test in the market. GARD®skin results can now be used for regulatory purposes in all OECD member countries. The approval now opens up not only these markets but also markets in non-OECD countries that are influenced by and apply the same regulatory frameworks. This breakthrough has led to a significant increase in inquiries and increased sales in the latter part of the year.

Growth via revenue synergies and new innovations

Our Italian subsidiary VitroScreen performed very well in its first year in the Group, recording its best year ever for GARD® sales. In addition, SenzaGen's commercial team secured a number of orders for VitroScreen's tests. During the year, their advisory services exceeded expectations and the Group's joint test offering for the medical devices market generated strong revenue synergies.

The year also saw several innovative collaboration projects in progress within the Group. A couple of these were performed on behalf of customers and involved combining both companies' innovations in 3D models and genomics analysis. This type of solution is interesting to companies in industries such as cosmetics and pharmaceuticals that are looking for more detailed and data-rich information for identifying mechanisms of action.

ToxHub acquisition

We also continued to implement our acquisition strategy by acquiring ToxHub in late 2022. ToxHub has been successful at offer expert consulting on test strategies and regulatory services. With them in the Group, we are creating a complete solution for customers with high-tech tests and services, can share business relationships along with access to several capabilities for helping customers through the entire regulatory process. The acquisition is an important addition to our business, contributing solid profitability and growth.

Looking ahead

I am very proud of the outstanding performance of our team in 2022. In 2023, we will move forward on increasing our market share in Europe with strong offerings in our prioritized industries. We will also expand our activities in the US market following the recent legislative change. We will continue to actively work on our acquisition agenda as well.

With our OECD-approved GARD® test, new innovative solutions and a broader offering in a market that is continuing to grow from technological, regulatory and ethical drivers, I can see us in a very favorable position for continued high growth.

Peter Nählstedt, President and CEO

SenzaGen at a glance

Vision

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

Business concept

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

Growth strategy

SenzaGen’s growth strategy is centered around continued commercialization of its proprietary GARD® and ORA® test platforms, expansion of its test portfolio and acquisitions of profitable and growing companies with cutting-edge complementary offerings.

A market with great potential

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

Our contribution to a more sustainable world

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





Innovative *in vitro* offering.

The SenzaGen Group offers complete solutions for assessing the safety of chemicals in several industries.

SenzaGen became an operating company in 2014. Prior to its founding, the EU had decided to no longer allow sales of cosmetic products tested on animals. This ban then spread to other countries and there are also processes in other industries in which there is an aim to avoid animal testing. Since then, the Company’s innovative and patent-protected GARD® test platform, based on genomics and machine learning, has been developed to determine whether substances can cause allergic reactions, and more complementary tests and services have been added.

VitroScreen, which was acquired, has vast expertise in human 3D tissue models. The patent-protected organoid platform (ORA®), which is uniquely produced by allowing human cells to self-organize without the need for artificial scaffolding, makes it possible to test the efficacy and safety of substances. The platform can be customized based on customer needs and constitutes a growing share of the VitroScreen’s sales. The combination and availability of the Group’s technologies open up new commercial opportunities.

ToxHub, the latest acquisition, specializes in toxicological risk assessment and regulatory strategy consulting, with expertise in medical devices and pharmacology.

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

Glossary
In vitro: Latin for “in glass”. In vitro tests are done in test tubes.
 Toxicology: A science that deals with poisons and poisoning symptoms, including how drugs and other chemicals can cause various adverse health effects in humans.

Sales, earnings and investments

Full year

Consolidated net sales for full year 2022 totaled SEK 41.8 (15.4) million, a 171% year-on-year increase. Organic sales accounted for SEK 21.5 (12.2) million, corresponding to a 77% increase, and acquired sales contributed SEK 20.3 (3.3) million.

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

Consolidated gross profit was SEK 27.3 (9.5) million, corresponding to a gross margin of 65% (61%). This improvement is attributable to both acquired and existing operations.

Operating expenses for the year totaled SEK 53.6 (41.5) million. The increase in costs is attributable to forward-looking investments in line with the Company's growth strategy, which includes the acquisitions of VitroScreen (Nov 2021) and ToxHub (Nov 2022). Operating expenses include depreciation and amortization amounting to SEK 9.4 (4.3) million, and SEK 4.9 (0.3) million of this amount is for depreciation and amortization on acquired assets.

Excluding acquisitions, depreciation and amortization, operating expenses increased by SEK 6.3 million or 17% year-on-year while revenue increased by 171%.

Consolidated EBITDA amounted to SEK -15.7 (-27.3) 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 2,0 (2.3) million, with patents and trademarks accounting for SEK 2,0 (2.3) million of this amount.

Capitalized expenditure for in-house development projects totaled SEK 0 (31) thousand.

Second half year

Consolidated net sales for the period amounted to SEK 21.8 (10.4) million, a 110 percent year-on-year increase. Organic sales accounted for SEK 12.1 (7.1) million, corresponding to a 70% increase, and acquired sales contributed SEK 9.7 (3.3) million.

Consolidated gross profit was SEK 14.7 (6.5) million.

Operating expenses for the period totaled SEK 26.6 (24.1) million. Excluding acquisitions, depreciation and amortization, operating expenses decreased by SEK 0.8 million year-on-year.

Consolidated EBITDA amounted to SEK -6,6 (-15.5) million.

ToxHub s.r.l. acquisition

On 11 November 2022, SenzaGen acquired ToxHub s.r.l., an Italian company. ToxHub specializes in toxicological risk assessment and regulatory strategy consulting, with specific expertise in medical devices and pharmacology. The company has three employees and reported approximately EUR 0.5 million in sales for 2022.

The price for 100% of the shares in ToxHub comprises initial consideration of EUR 0.47 million and multiple components of additional consideration of up to EUR 0.4 million in 2024–2025. These additional consideration components are contingent on achieving certain financial targets. The initial consideration consists of EUR 0.32 million in cash and EUR 0.15 million in consideration shares.

The total consideration paid amounted to SEK 5.1 million. SEK 0.4 million of this consideration is attributable to goodwill, while the other SEK 4.7 million is attributable to intellectual property rights, equity and deferred tax on surplus values.

Funding

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

Net cash from operating activities for the year was SEK -16,0 (-21.0) million. Cash flow was impacted by increased trade receivables amounting to SEK 9.1 (6.3) million due to deliveries at the end of the period.

Total net cash flow for the year amounted to SEK -29.2 (-20.2) million.

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

The 2022 Annual General Meeting (AGM) resolved to authorize the board to resolve to issue new shares, of which the combined total results in no more than a 20% increase in share capital based on the total share capital at the time of the 2022 AGM.

Under the 2022 AGM authorization, a non-cash issue of 123,409 shares was conducted, which increased the share capital by SEK 6,170.45. The total number of shares at year-end was 24,188,325.

Parent Company

The Parent Company's net sales for the January-December 2022 period totaled SEK 21.5 (12.2) million. The loss before tax was SEK -21.4 (-31.3) million.

The Parent Company's net investments in both property, plant and equipment and intangible assets for the year amounted to SEK 2.3 (2.5) million, and its total cash flow was SEK -31.1 (-21.6) million.

Additional consideration was paid during the year totaling SEK 5.1 million attributable to the acquisition of VitroScreen s.r.l. The amount of the additional consideration paid was in line with previous estimates.

For further information, see the disclosures for the Group.

Other information

Group

SenzaGen AB (publ) (reg. no. 556821-9207), based in Lund, is the parent company of subsidiary SenzaGen North America Inc, based in North Carolina, USA (reg. no. C3870650), subsidiary VitroScreen s.r.l. (reg. no. 13454040158) based in Milan, Italy, and subsidiary ToxHub s.r.l. (reg. no. 15737021004) based in Rome, Italy.

Segment reporting

SenzaGen's business currently includes only one operating segment, toxicology *in vitro* testing. Therefore, see the income statement and balance sheet for operating segment reporting.

Accounting policies

The accounting policies applied are in compliance with the Swedish Annual Accounts Act (1995:1554) and the general advice of the Swedish Accounting Standards Board in BFNAR 2012:1 Annual Reports and Consolidated Financial Statements ("K3"). The same accounting policies and calculation bases were applied as those in the 2021 Annual Report.

Operating activities are conducted in the parent company and two subsidiaries, VitroScreen and ToxHub.

Information about risks and uncertainties

SenzaGen's business is exposed to several risks, including both operational and financial risks. The operational risks mainly comprise uncertainty concerning product development, supplier agreements, product liability and distribution. For a more detailed description of the risks and uncertainties to which SenzaGen is exposed, see the risk and sensitivity analysis in the 2021 Annual Report.

Research and development

SenzaGen invests in focused research to drive the development of cutting-edge new products that provide the human-relevant *in vitro* methods required 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 ORA®, the Group can also provide customers with tailored solutions for a specific test method, cell or organ type.

Employees

At the end of the period, the Group had 35 (31) employees, 24 (19) of which were women and 11 (12) were men. At the end of the period, the Parent Company had 21 (20) employees, 13 (11) of which were women and 8 (9) were men.

Significant events after the end of the year

There are no significant post year events to report.

Proposed dividend

The board proposes that no dividend be paid to the Company's shareholders.

Audit

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

2023 AGM

SenzaGen's 2023 Annual General Meeting (AGM) will be held on 4 May at 4 PM in Medicon Village's conference rooms at Scheeletorget 1, Lund, Sweden. Shareholders who wish to have an item deliberated on at the AGM may send a written request by email to ir@senzagen.com or by regular mail to: Styrelsen, SenzaGen AB, Medicon Village, 223 81 Lund. Such requests must be received no later than seven weeks prior to the AGM to be eligible for inclusion in the meeting notice and, consequently, the AGM agenda.

Certified Adviser

FNCA Sweden AB is the Company's Certified Adviser on Nasdaq First North.

Financial calendar

2022 Annual Report week 13-14 2022
2023 AGM 4 May 2023
January-June 2023 Interim Report 24 August 2023

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

The board of directors and CEO assure that the interim report provides a true and fair view of the Parent Company and Group's business, financial position and financial performance and discloses significant risks and uncertainties to which the Parent Company and Group companies are exposed.

Lund, 16 February 2023

Carl Borrebaeck
Chairman

Laura Chirica
Director

Anki Malmborg Hager
Director

Ian Kimber
Director

Paul Yianni
Director

Paula Zeilon
Director

Peter Nählstedt
CEO

For questions about this report, contact:

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Publication

This information constitutes the type of information SenzaGen AB is required to publish under the EU Market Abuse Regulation. This information was released for publication by the contact person set out above on 16 February 2023 at 08:30 AM CET.

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SenzaGen is listed on Nasdaq First North. The Company is traded under the ticker symbol SENZA and ISIN code SE0010219626.

Condensed consolidated statement of comprehensive income (SEK thousand)	Jul-Dec 2022	Jul-Dec 2021	Full year 2022	Full year 2021
Operating income				
Net sales	21,848	10,407	41,770	15,422
Cost of goods sold	-7,186	-3,877	-14,434	-5,969
Gross profit/loss	14,662	6,530	27,336	9,453
Selling expenses	-10,929	-11,189	-21,609	-21,234
Administrative expenses	-8,528	-9,892	-17,418	-15,550
Research and development expenditure	-4,202	-2,613	-8,985	-3,874
Acquisition-related costs	-2,584	-293	-4,921	-293
Other operating income	495	321	1,189	542
Other operating expenses	-350	-695	-703	-870
Operating profit/loss	-11,436	-17,538	-25,111	-31,533
Profit/loss from financial items				
Interest income and similar items	61	90	338	187
Interest expenses and similar items	-143	-17	-189	-19
Profit/loss after financial items	-11,518	-17,465	-24,962	-31,365
Tax expenses	101	19	50	19
Profit/loss for the period	-11,417	-17,446	-24,912	-31,346
Share of profit/loss to Parent Company shareholders	-11,417	-17,446	-24,912	-31,346

Per share data	Jul-Dec 2022	Jul-Dec 2021	Full year 2022	Full year 2021
Earnings per share (SEK)	-0,47	-0,78	-1,03	-1,35
Fully diluted earnings per share (SEK)	-0,47	-0,78	-1,03	-1,35
Equity per share (SEK)	3,71	4,58	3,71	4,58
Equity ratio (%)	75%	82%	75%	82%
Number of outstanding shares at end of period (thousands)	24,188	24,065	24,188	24,065
Average number of outstanding shares (thousands)	24,106	22,260	24,085	23,162
Share price at end of period (SEK)	12,05	10,00	12,05	10,00

Definitions of financial ratios

Earnings per share

Profit/loss for the period as a percentage of weighted average number of shares.

Equity per share

Equity as a percentage of the number of shares at the end of the period.

Equity ratio

Equity as a percentage of total assets.

Condensed consolidated statement of financial position (SEK thousand)	31 Dec 2022	30 June 2022	31 Dec 2021
Assets			
Goodwill	21,647	12,307	13,109
Intangible assets	38,107	35,184	36,061
Property, plant and equipment	2,575	2,745	3,230
Inventories	3,614	3,705	3,201
Trade receivables	9,094	8,916	6,269
Other receivables	4,941	3,771	2,771
Cash and cash equivalents	39,976	49,034	69,164
Total assets	119,954	115,662	133,805
Equity and liabilities			
Equity	89,701	98,053	110,243
Non-interest-bearing current liabilities	3,795	2,507	3,910
Interest-bearing current liabilities	1,330	912	726
Trade payables	4,420	3,693	3,135
Other liabilities	18,005	7,280	11,981
Accrued expenses and deferred income	2,703	3,217	3,810
Total equity and liabilities	119,954	115,662	133,805
Statement of changes in equity (SEK thousand)	31 Dec 2022	30 June 2022	31 Dec 2021
Opening balance	110,243	110,243	107,792
New shares issue	-	-	30,008
Non-cash issue	1,629	-	6,126
Costs new shares issue	-42	-	-2,307
Effect of employee stock option plan	-	-	-344
Profit/loss for the period	-24,902	-13,495	-31,346
Foreign currency effect	2,783	-1,305	314
Equity at end of period	89,701	98,053	110,243

Condensed consolidated statement of cash flows (SEK thousand)	Jul-Dec 2022	Jul-Dec 2021	Full year 2022	Full year 2021
Operating profit/loss after tax	-11,417	-17,446	-24,912	-31,346
Adjustments for non-cash items	4,748	2,349	9,145	4,236
Net cash from operating activities before changes in working capital	-6,669	-15,097	-15,767	-27,110
Changes in working capital	9,638	7,038	-304	6,130
Net cash from operating activities	2,969	-8,059	-16,071	-20,980
Acquisitions/disposals of intangible assets	-1,311	-1,571	-1,982	-2,334
Acquisitions/disposals of property, plant and equipment	-447	-235	-607	-331
Acquisitions/disposals of subsidiaries	-13,041		-13,041	
Acquisitions/disposals of financial assets	2,193	-23,890	2,193	-23,890
Net cash from investing activities	-12,606	-25,696	-13,437	-26,555
New share issue	-	30,008	-	30,008
Transaction expenses attributable to new share issue	-42	-2,306	-42	2,306
Option premium	-	-	-	8
Repurchase of options	-	-352	-	-352
Change in long term debt to credit institutions	469	-68	73	-68
Net cash from financing activities	427	27,282	31	27,290
Total cash flow for the period	-9,210	-6,473	-29,477	-20,245
Cash and cash equivalents at start of period	49,034	75,571	69,164	89,343
Translation difference on cash and cash equivalents	152	66	289	66
Cash and cash equivalents at end of period	39,976	69,164	39,976	69,164

Parent Company income statement (SEK thousand)	Jul-Dec 2022	Jul-Dec 2021	Full year 2022	Full year 2021
Operating income				
Net sales	12,122	7,149	21,501	12,164
Cost of goods sold	-4,120	-2,478	-7,430	-4,570
Gross profit/loss	8,002	4,671	14,071	7,594
Selling expenses	-10,579	-11,053	-20,534	-21,143
Administrative expenses	-5,551	-8,974	-12,041	-14,632
Research and development expenditure	-1,485	-1,774	-3,543	-3,035
Other operating income	487	233	1,150	454
Other operating expenses	-349	-402	-699	-577
Operating profit/loss	-9,475	-17,299	-21,596	-31,339
Profit/loss from financial items				
Interest income and similar items	97	93	356	190
Interest expenses and similar items	-110	2	-117	-
Profit/loss after financial items	-9,488	-17,204	-21,357	-31,149
Tax expenses	-	-	-	-
Profit/loss for the period	-9,488	-17,204	-21,357	-31,149

Parent Company balance sheet (SEK thousand)	31 Dec 2022	30 June 2022	31 Dec 2021
Assets			
Intangible assets	-13,715	13,949	14,761
Property, plant and equipment	861	942	1,370
Financial assets	46,103	31,101	31,101
Intentories	973	1,491	1,185
Trade receivables	3,405	5,202	3,144
Receivables from Group companies	1,252	1,226	1,085
Other liabilities	1,343	1,672	1,376
Prepaid expenses and accrued income	4,180	2,441	1,361
Cash and bank balances	36,242	47,495	67,332
Total assets	108,074	105,519	122,715
Equity and liabilities			
Equity	90,744	98,645	110,513
Non-interest-bearing current liabilities	1,162	1,339	1,212
Trade payables	2,989	1,744	1,598
Other liabilities	2,398	2,868	3,139
Accrued expenses and deferred income	10,781	923	6,253
Total equity and liabilities	108,074	105,519	122,715

Acquisition analysis ToxHub s.r.l. (SEK thousand)	2022
Fair value of acquired assets and assumed liabilities	
Intangible assets, excluding goodwill	3,194
Goodwill	436
Property, plant and equipment	68
Current assets, excluding cash and cash equivalents	1,601
Cash and cash equivalents	2,193
Provisions	0
Non-current liabilities	-796
Current liabilities	-1,595
Total fair value of acquired net assets	5,102
Acquisition paid for with:	
Cash	3,473
Non-cash issue of shares in SenzaGen AB	1,629
Total	5,102