

Sales quadrupled and the Company obtained OECD approval for GARD[®]skin

» In the first half year, the Company delivered exceptionally strong growth with record-high orders and we achieved a key breakthrough for our technology with the OECD approval of GARD[®]skin. We also secured new patents, delivered intra-Group revenue synergies and kicked off development projects for the next generation of non-animal testing. With the OECD approval in hand, we expect increased demand for our GARD[®] tests. As a result, we are now adding more operational capacity to be able to sell and perform more tests. I am very proud to lead this successful team and to deliver non-animal tests with new technology to the world's leading medical device, pharmaceuticals, chemicals and cosmetics companies.”



Peter Nählstedt, President and CEO

Half year 1 January–30 June

- » Net sales totaled SEK 19.9 (5.0) million.
- » The operating loss was SEK -13.7 (-14.0) million.
- » Earnings per share were SEK -0.56 (-0.65).
- » Cash and cash equivalents at 30 June amounted to SEK 49.0 (75.6) million.

Significant events during the first half year

- » SenzaGen obtained OECD approval for GARD[®]skin – a breakthrough providing access to significantly larger markets, which creates prospects for increased sales.
- » SenzaGen secured its largest order for non-animal testing with GARD[®]skin Dose-Response valued at SEK 4.3 million.
- » SenzaGen received a follow-on order for GARD[®]skin and GARD[®]potency valued at SEK 0.7 million from a global US-based world leader in chemicals.
- » SenzaGen received another order from RIFM for non-animal photosensitization testing with GARD[®]skin Dose-Response worth SEK 1.5 million.
- » SenzaGen broadened its non-animal offering for medical devices with more tests and toxicology consulting services, establishing itself deeper in the market and realizing acquisition synergies.

Significant events after the end of the period

- » SenzaGen performs its largest test order for GARD[®]skin to date – valued at approximately SEK 1 million.

Message from the CEO

In the first half year, the Company delivered exceptionally strong growth with record-high orders, and we achieved a key breakthrough for our technology with the OECD approval of GARD®skin. We also secured new patents, delivered intra-Group revenue synergies and started new development projects for the next generation of non-animal testing.

The OECD approval

On 30 June 2022, a milestone announcement was made that the Company had been working towards since the final version of the application was submitted in 2017: GARD®skin has now been admitted to the OECD Test Guideline Program, obtaining approval via the program. GARD®skin test results can now be used for regulatory purposes in all OECD member countries. The approval opens up not only these markets to SenzaGen but also markets in non-OECD countries that are influenced by and apply the Test Guideline Program. Depending on the regulatory context, GARD®skin can be used as a stand-alone test for identifying skin allergens and can be used together with additional evidence for negative results. We expect to see increase demand as a result of the approval and are prepared to meet this demand with our GLP labs staffed by highly skilled employees, an established commercial organization with distributors and three strong CROs.

Exceptionally strong growth

In the first half of the year, SenzaGen's organic sales were very strong, totaling SEK 9.4 million, which is equivalent to 87% growth. Our sales from acquisitions contributed SEK 10.5 million as VitroScreen also delivered a strong first half year well in line with the Group's expectations. Altogether, our consolidated sales reached SEK 19.9 million, representing growth as high as 297%, and we continued to maintain effective cost controls.

The number of orders received was strong in the first half year. We secured our two largest orders ever for GARD®skin Dose-Response, the first valued at SEK 1.5 million and the second as much as SEK 4.2 million. In addition, we received our largest order ever for GARD®skin from a US chemicals company for approximately SEK 1 million as well as an SEK 700,000 follow-on order from an existing customer.

As a result, we head into the second half year with a strong order backlog and will very actively work on our customer engagement. Moreover, we will present our offering at several key toxicology trade fairs, at which we naturally will focus on spreading the word that the world's first genomics-based toxicology test has now been approved by the OECD.

Broadened non-animal offering for medical devices

With VitroScreen in the Group, SenzaGen has created new opportunities for expansion via revenue synergies. At the start of the year, we launched a joint test and service offering targeting the substantial medical devices market, in which we see growing interest in non-animal solutions, especially in Europe. This initiative worked out well and in just the first weeks following the launch, a leading medical device company, an existing customer of SenzaGen, ordered advisory services from VitroScreen. After that, we received several orders for biocompatibility testing.

New development projects

We are engaged in several projects within the Group to both develop new non-animal tests and obtain regulatory approval for the tests that have already been developed.

SenzaGen and VitroScreen have combined their expertise in the development of completely new innovative solutions applying 3D-cell models and data analysis based on SenzaGen's genomics platform. We are working on this type of development project in order to meet customer needs for more powerful new methods to replace animal studies.

We are also proceeding with the validation of the GARD® platform by generating supplementary data for GARD®potency in order to eventually also achieve OECD approval for this test that determines whether a substance is a strong or weak allergen, which is of great importance in risk assessment.

Patent and IP portfolio

A strong patent portfolio and trademark protection are strategically important puzzle pieces for our continued expansion. The Group's patent portfolio comprises 6 patent families covering tests in key markets. In addition, the Company acquired trademark rights in prioritized markets.

In the first half of 2022, the Company obtained granted patents for GARD®potency in the US, Japan and South Korea. Additionally, the portfolio was strengthened with patents in Europe for SenzaCell™, which is the central cell line used in all GARD® tests, and for a future development area, GARD®protein. We also expanded our trademark protection for GARD® with registration in the US.

Looking ahead

With the OECD approval in hand, we expect increased demand for our GARD® tests. As a result, we are now adding more operational capacity to be able to sell and perform more tests. I am very proud to lead this successful team and to deliver non-animal tests with new technology to the world's leading medical device, pharmaceuticals, chemicals and cosmetics companies.

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

Growth strategy

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

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

A market with great potential

The *in vitro* toxicology testing market is global and growing strongly. Following the expansion of the Company's range of tests and the VitroScreen acquisition, 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.

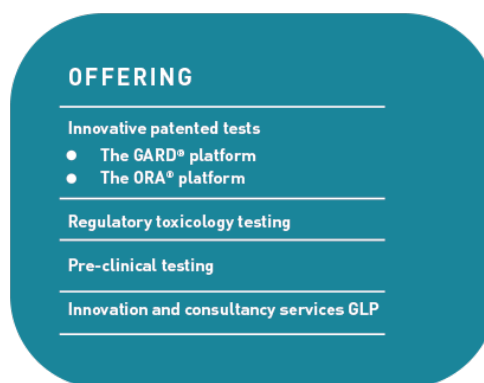
Our contribution

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

Innovative *in vitro* offering.

SenzaGen became an operating company in 2014. Prior to its founding, the EU had decided to no longer allow sales of cosmetic products tested on animals. This ban then spread to other countries and there are also processes in other industries in which there is an aim to avoid animal testing. Since then, the Company's innovative 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. Its 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 company's sales. The combination and availability of the Group's unique technologies opens up new commercial opportunities.



Glossary

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

ESAC: The EURL ECVAM Scientific Advisory Committee.

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

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

Sales, earnings and investments

First half year

Consolidated net sales for the January-June 2022 period amounted to SEK 19.9 (5.0) million, a 297 percent year-on-year increase. Organic sales accounted for SEK 9.4 (5.0) million and acquired sales contributed SEK 10.5 million.

Consolidated gross profit was SEK 12.7 (2.9) million.

Operating expenses for the period totaled SEK 27.0 (17.2) million. The increase in costs is attributable to forward-looking investments in line with the Company's growth strategy, which includes acquisitions. The VitroScreen acquisition resulted in the number of employees increasing by 10 from the same period in 2021.

Operating expenses include depreciation and amortization amounting to SEK 4.6 (1.9) million, and SEK 2.3 (0) million of this amount is for depreciation and amortization on acquired assets.

The consolidated operating loss was SEK -13.7 (-14.0) million.

SenzaGen capitalizes new development expenditure and recognizes patents in the balance sheet on an ongoing basis. Total investments in intangible assets for the period were SEK 0.7 (0.8) million, with patents and trademarks accounting for SEK 0.7 (0.7) million of this amount. Capitalized expenditure for in-house development projects totaled SEK 0 (0.03) million.

Funding

The Group's cash and cash equivalents at the end of the period totaled SEK 49.0 (75.6) million.

Net cash from operating activities for the period was SEK -19.0 (-12.9) million. Cash flow was impacted by increased trade receivables amounting to SEK 8.9 (1.8) million due to deliveries at the end of the period.

Total net cash flow for the period amounted to SEK -20.3 (-13.8) million.

Parent Company

The Parent Company's net sales for the January-June 2022 period totaled SEK 9.4 (5.0) million. The loss before tax was SEK -11.9 (-13.9) million.

The Parent Company's operating loss was SEK -12.1 (-14.0) million.

The Parent Company's net investments in both property, plant and equipment and intangible assets for the period amounted to SEK 0.7 (0.9) million, and its total cash flow was SEK -19.8 (-13.8) million.

Additional consideration was paid during the period 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) and subsidiary VitroScreen s.r.l. (reg. no. 13454040158) based in Milan, 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 subsidiary VitroScreen.

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 conducts research projects to strengthen its product portfolio. The foundation of the Group's product development is the GARD® technology platform, which is broadly applicable in all of the Company's relevant industries and for difficult-to-test substances. The GARD®

technology platform also has potential for use in several more testing and application domains. With the help of VitroScreen's proprietary organoid model ORA®, the Group can also provide customers with tailored solutions for a specific test method, cell or organ type.

Employees

At the end of the period, the Group had 29 (19) employees, 18 (10) of which were women and 11 (9) were men. At the end of the period, the Parent Company had 18 (19) employees, 10 (10) of which were women and 8 (9) were men.

Significant events after the end of the period

On 11 August, SenzaGen announced that the Company had been selected to test substances for a new customer, a world leader in the chemicals industry, for a total value of approximately SEK 1 million. The order, which is the single largest for GARD®skin and also the largest from a chemicals company, was received in the second quarter and will be completed in the third quarter of 2022 at SenzaGen's GLP-certified laboratory in Lund. The customer aims to use GARD®skin to obtain more detailed information about the skin sensitizing effect of substances traditionally considered difficult to test with the conventional OECD-approved test methods, thus expanding its reference library.

Audit

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

Certified Adviser

FNCA Sweden AB is the Company's Certified Adviser on Nasdaq First North.
Phone: +46 8-528 00 399 | info@fnca.se

Financial calendar

2022 Year-End Report

16 February 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, 18 August 2022

Carl Borrebaeck
Chairman

Laura Chirica
Director

Anki Malmborg Hager
Director

Ian Kimber
Director

Paul Yianni
Director

Paula Zeilon
Director

Peter Nählstedt
President and CEO

For questions about this report, contact:

Peter Nählstedt, President and CEO, SenzaGen AB

Tel: +46 700-23 44 31 | Email: peter.nahlstedt@senzagen.com

Marianne Olsson, VP Finance, SenzaGen AB

Tel: +46 706-36 73 18 | Email: marianne.olsson@senzagen.com

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 18 August 2022 at 1:00 PM CEST.

Address

SenzaGen AB (publ) | Company registration number: 556821-9207

Bldg 401, Medicon Village, 223 81 LUND, SWEDEN

Phone: +46 46-275 60 00 | info@senzagen.se | www.senzagen.com

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)	Jan-Jun 2022	Jan-Jun 2021	Full year 2021
Operating income			
Net sales	19,922	5,015	15,422
Cost of goods sold	-7,248	-2,092	-5,969
Gross profit/loss	12,674	2,923	9,453
Selling expenses	-10,680	-10,045	-21,234
Administrative expenses	-8,890	-5,658	-15,550
Research and development expenditure	-4,783	-1,261	-3,874
Acquisition-related costs	-2,337	-	-293
Other operating income	694	221	542
Other operating expenses	-353	-175	-577
Operating profit/loss	-13,675	-13,995	-31,533
Profit/loss from financial items			
Interest income and similar items	277	97	187
Interest expenses and similar items	-46	-2	-19
Profit/loss after financial items	-13,444	-13,900	-31,365
Tax expenses	-51	-	19
Profit/loss for the period	-13,495	-13,900	-31,346
Share of profit/loss to Parent Company shareholders	-13,495	-13,900	-31,346

Per share data	Jan-Jun 2022	Jan-Jun 2021	Full year 2021
Earnings per share (SEK)	-0,56	-0,65	-1,35
Fully diluted earnings per share (SEK)	-0,56	-0,65	-1,35
Equity per share (SEK)	4,07	4,40	4,58
Equity ratio (%)	85%	96%	82%
Number of outstanding shares at end of period (thousands)	24,065	21,358	24,065
Average number of outstanding shares (thousands)	24,065	21,358	23,162
Share price at end of period (SEK)	9,20	18,50	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]	30 June 2022	30 June 2021	31 Dec 2021
Assets			
Goodwill	12,307	-	13,109
Intangible assets	35,184	14,741	36,061
Property, plant and equipment	2,745	1,669	3,230
Inventories	3,705	1,284	3,201
Trade receivables	8,916	1,795	6,269
Other receivables	3,771	2,783	2,771
Cash and cash equivalents	49,034	75,571	69,164
Total assets	115,662	97,843	133,805
Equity and liabilities			
Equity	98,053	93,874	110,243
Non-interest-bearing current liabilities	2,507	1,465	3,910
Interest-bearing current liabilities	912	-	726
Trade payables	3,693	686	3,135
Accrued expenses and deferred income	3,217	1,216	3,810
Other liabilities	7,280	602	11,981
Total equity and liabilities	115,662	97,843	133,805
Statement of changes in equity [SEK thousand]	30 June 2022	30 June 2021	31 Dec 2021
Opening balance	110,243	107,792	107,792
New shares issue	-	-	30,008
Non-cash issue	-	-	6,126
Costs new shares issue	-	-	-2,307
Effect of employee stock option plan	-	8	-344
Profit/loss for the period	-13,495	-13,900	-31,346
Foreign currency effect	-1,305	-26	314
Equity at end of period	98,053	93,874	110,243

Condensed consolidated statement of cash flows (SEK thousand)	Jan-Jun 2022	Jan-Jun 2021	Full year 2021
Operating profit/loss after tax	-13,495	-13,900	-31,346
Adjustments for non-cash items	4,397	1,887	4,236
Net cash from operating activities before changes in working capital	-9,098	-12,013	-27,110
Changes in working capital	-9,942	-908	6,130
Net cash from operating activities	-19,040	12,921	-20,980
Acquisitions/disposals of intangible assets	-670	-763	-2,334
Acquisitions/disposals of property, plant and equipment	-160	-96	-331
Acquisitions/disposals of subsidiaries	-	-	-23,890
Net cash from investing activities	-830	-859	-26,555
New share issue	-	-	30,008
Transaction expenses attributable to new share issue	-	-	-2,306
Option premium	-	8	8
Repurchase of options	-	-	-352
Change in long term debt to credit institutions	-396	-	-68
Net cash from financing activities	-396	8	27,290
Total cash flow for the period	-20,266	-13,772	-20,245
Cash and cash equivalents at start of period	69,164	89,343	89,343
Translation difference on cash and cash equivalents	136	-	66
Cash and cash equivalents at end of period	49,034	75,571	69,164

Parent Company income statement (SEK thousand)	Jan-Jun 2022	Jan-Jun 2021	Full year 2021
Operating income			
Net sales	9,379	5,015	12,164
Cost of goods sold	-3,310	-2,092	-4,570
Gross profit/loss	6,069	2,923	7,594
Selling expenses	-9,955	-10,090	-21,143
Administrative expenses	-6,490	-5,658	-14,632
Research and development expenditure	-2,058	-1,261	-3,035
Other operating income	663	221	454
Other operating expenses	-350	-175	-577
Operating profit/loss	-12,121	-14,040	-31,339
Profit/loss from financial items			
Interest income and similar items	259	97	190
Interest expenses and similar items	-7	-2	-
Profit/loss after financial items	-11,869	-13,945	-31,149
Tax expenses	-	-	-
Profit/loss for the period	-11,869	-13,945	-31,149

Parent Company balance sheet (SEK thousand)	30 June 2022	30 June 2021	31 Dec 2021
Assets			
Intangible assets	13,949	14,741	14,761
Property, plant and equipment	942	1,669	1,370
Financial assets	31,101	84	31,101
Intentories	1,491	1,284	1,185
Trade receivables	5,202	1,795	3,144
Receivables from Group companies	1,226	1,021	1,085
Other receivables	1,672	1,458	1,376
Prepaid expenses and accrued income	2,441	1,324	1,361
Cash and bank balances	47,495	75,158	67,332
Total assets	105,519	98,534	122,715
Equity and liabilities			
Equity	98,645	94,243	110,513
Non-interest-bearing current liabilities	1,339	1,465	1,212
Trade payables	1,744	1,008	1,598
Other liabilities	2,868	1,216	3,651
Accrued expenses and deferred income	923	602	5,741
Total equity and liabilities	105,519	98,534	122,715