



Interim report first quarter 2023

Toleranzia AB (publ) | 556877-2866



INTERIM REPORT FIRST QUARTER 2023 TOLERANZIA AB (PUBL)

Three months, January 1 - March 31

- Net sales amounted to -- KSEK (--)
- Profit after financial items amounted to KSEK -1,947 (-2,072).
- Cash flow from operating activities amounted to SEK -2,205 thousand (-2,395).
- Investments in intangible assets amounted to SEK 10,132 thousand (8,079).
- Earnings per share amounted to SEK -0.02 (-0.02).

The "Company" or "Toleranzia" refers to Toleranzia AB with organization number 556877-2866.

Significant events in the first quarter of 2023

- The composition of the Nomination Committee for the 2023 AGM was announced.
- A patent application was filed to protect combination therapy with the Company's tolerogens.
- A technical batch of TOL2 was produced for use in the upcoming GLP toxicology study.
- A financial contribution of approximately SEK 1.7 million was granted by the Swedish innovation agency Vinnova within the call "Swelife and Medtech4Health - Collaborative projects for better health".

Key financial data

	2023-01-01 2023-03-31 3 months	2022-01-01 2022-03-31 3 months	2022-01-01 2022-12-31 12 months
Net sales KSEK	-	-	-
Operating profit/loss KSEK	- 1 988	- 2 072	- 8 639
Profit/loss for the period KSEK	- 1 947	- 2 072	- 8 456
Total assets KSEK	123 084	131 537	125 632
Cash flow for the period KSEK	- 12 337	- 10 474	- 42 341
Cash and bank balances KSEK	21 600	65 804	33 937
Equity KSEK	117 562	125 893	119 509
Earnings per share SEK	- 0,02	- 0,02	- 0,08
Equity/assets ratio (%)	95,5	95,1	-
Number of shares at the end of the period (no.)	110 315 231	110 315 231	110 315 231
Average number of shares (no.)	110 315 231	110 315 231	110 315 231
Number of employees and consultants	10	6	8

COMMENTS FROM THE CEO



2023 begins with several major achievements

In the first quarter of 2023, we took several major steps forward. We completed the manufacturing of a technical batch of TOL2 for the upcoming GLP toxicology study, which means we are another step closer to the first clinical trial in patients. We also strengthened the patent protection for our tolerance technology and were awarded a grant from Vinnova to start an expanded research project in ANCA vasculitis.

At the end of the quarter, a so-called technical batch of TOL2 was successfully produced - the second large-scale production. It gave the same high yield of purified TOL2 as the pilot batch that we produced at the end of 2022 and it is gratifying that we now have an efficient and robust manufacturing process for large-scale production in place. The material from the technical batch will be used in the upcoming GLP toxicology study. The next step will be to produce a GMP batch for use in the planned clinical trials in patients with myasthenia gravis. The work to develop a final formulation for the drug substance is ongoing and initial results indicate that it could be a freeze-dried product, which could provide significant benefits in terms of simplified storage and distribution as well as increased shelf life.

Following several preclinical studies with combination therapies, we have now filed a new patent application for the treatment of autoimmune diseases with tolerogens in combination with other immunomodulatory agents. Our drug development team made the surprising discovery that specific combinations of protein-based tolerogens and immunomodulatory agents provide synergies that can dramatically increase the therapeutic effect in the treatment of autoimmune diseases. The patent application covers this concept, and we see great potential for the discovery both in our current development programs and for our tolerance technology in general.

Before we rounded off the quarter, we were informed that we had been awarded a grant from Vinnova to start an expanded research project in the autoimmune blood vessel disease ANCA vasculitis. The project aims to use completely new technology to examine patients with ANCA vasculitis to increase detailed knowledge of the root cause of the disease. The knowledge can be directly used for the continued development of our drug candidate TOL3, which is based on the Company's tolerance technology. The project will be run by Toleranzia in collaboration with Lund University's Kidney Research Lab, Region Skåne and SciCross AB.

In February, we presented Toleranzia's development project at the 6th Antigen-Specific Immune Tolerance Summit in Boston, USA. The meeting highlighted the significant progress being made in the field of immune tolerance and tolerance induction right now, which makes it incredibly exciting to be a key player in this arena.

With great confidence in the future and the potential of our technology to change the lives of patients with autoimmune diseases, we look forward to completing the production process and the GLP toxicology study which are the final steps before we can initiate our first clinical study of TOL2 in patients with myasthenia gravis. In parallel, we are running the expanded project in ANCA vasculitis and continue to evaluate the possibilities of different combination therapies in our ongoing and future drug projects.

Charlotte Fribert
Executive Director
Gothenburg, May 2, 2023

ABOUT TOLERANZIA

General information about the business

Toleranzia AB (556877-2866) is a Swedish biotechnology company listed on Nasdaq First North. The Company develops drugs that harness the power of the immune system for the treatment of autoimmune orphan diseases (rare diseases). The drugs, which target the cause of the disease, can alleviate or cure the disease and not, like current treatments, merely reduce the symptoms. They have the potential to be the first long-acting or curative therapies that act specifically on the underlying cause of the autoimmune orphan disease for which they are being developed. Toleranzia's main focus is the autoimmune nerve and muscle disease myasthenia gravis, for which the Company is developing the drug candidate TOL2. In addition, Toleranzia is working on the autoimmune blood vessel disease ANCA-vasculitis, for which the Company is developing the drug candidate TOL3. Both diseases are so-called orphan diseases and there is a great medical need and market potential for both. For further information, please visit: www.toleranzia.com.

Company structure and shareholding

Toleranzia was founded by researchers at the University of Gothenburg. The company operates at the Biotech Center in Gothenburg. Toleranzia has no subsidiaries and is not part of any group. Nor does the company have any shareholdings in other companies.

Financial development and position

Period January - March

Net sales amounted to -- KSEK (--) during the quarter.

Other income amounted to KSEK 47 (21) during the quarter and consists mainly of currency exchange rate gains.

The company's operating expenses amounted to KSEK 12,168 (10,172) for the quarter, of which KSEK 1,353 (1,037) relates to personnel costs.

The increased costs are in line with the Company's plan and expectations linked to the long-term strategy. The cost of personnel has increased compared to the previous year, as a result of an increase in the number of human resources compared to previous quarters.

Of the total cost, KSEK 10,132 (8,079) relates to the development of the company's project portfolio in myasthenia gravis and ANCA vasculitis, where the costs incurred are capitalized on an ongoing basis as own-account work.

The operating result during the quarter amounted to KSEK -1,989 (-2,072).

Cash flow and liquidity

For the period January - March 2023, cash flow from operating activities amounted to KSEK -2,205 (-2,395).

As of March 31, 2023, the Company's cash and bank balance amounted to KSEK 21,600 (65,804).

Investments

Total investments in intangible assets amounted to KSEK 10,132 (8,079) for the period January - March 2023.

The investments relate to the development of the Company's project portfolio within myasthenia gravis and ANCA vasculitis and the costs are capitalized on an ongoing basis as own-account work.

Human resources

Toleranzia is a development company where dedicated employees with solid experience and expertise are a prerequisite for commercial success and for achieving the Company's vision. The Company had 10 full-time equivalent employees or contracted consultants as of March 31, 2023.

Financing

In the fall of 2021, the Company carried out a new share issue, raising capital and liquid funds totaling KSEK 69,532, before issue costs.

The company has a constant focus on cash flow and works continuously to secure financing. The Board of Directors and management have ongoing discussions with major shareholders and make the assessment that there are several possible alternatives and commitments to obtain long-term and sustainable financing of ongoing and future development projects and that the Company will continue to be satisfactorily financed.

In light of the above, the report has been prepared on a going concern basis as the management and Board of Directors believe that there are several options for obtaining long-term financing.

Related party transactions

The company has related party transactions regarding the purchase of services from the company NorthX Biologics Matfors AB in Matfors. Purchased services have been made on market terms.

Ongoing unrest in Europe

There is a general uncertainty in the market caused by the ongoing conflict in Ukraine. The uncertainty has so far not affected the company's operations and is not expected to affect operations in the coming months. Toleranzia has no operations in either the Russian or Ukrainian market. Raw materials and expertise are sourced from neither Russia nor Ukraine.

Shares

Toleranzia's shares are traded on Nasdaq First North Growth Market since October 15, 2020. The number of shares in Toleranzia amounted to 110,315,231 as of March 31, 2023. The share capital amounted to SEK 13,789,404 as of March 31, 2023. The Company has one class of shares, of which each share has a quota value of SEK 0.125 (SEK 0.125) and carries equal rights to participate in the Company's assets and earnings.

There are no ongoing option programs at the time of publication of this interim report.

Mangold Fondkommission AB is the Company's Certified Adviser and can be reached at: ca@mangold.se.

Ownership per March 31, 2023

Shareholder	Share of capital	Share of Votes
FLERIE INVEST AB	47,4%	47,4%
FÖRSÄKRINGSAKTIEBOLAGET AVANZA PENSION	2,7%	2,7%
NORDNET PENSIONS FÖRSÄKRING AB	2,5%	2,5%
S & B CHRISTENSEN AB	2,0%	2,0%
NORDEA LIVFÖRSÄKRING SVERIGE AB	1,8%	1,8%
BERGSTRÖM, NIKLAS TOBIAS	1,4%	1,4%
NORDIC TENDER AB	1,4%	1,4%
KONSTRUKTION O FÖRSÄLJNINGSAKTIEBOLAGET KFAB	1,1%	1,1%
BERNHULT, PER	0,9%	0,9%
NAVCAP AB	0,9%	0,9%
OTHERS	38,0%	38,0%
Total	100,0%	100,0%

Review by the auditor

This interim report has not been reviewed by the Company's auditors.

Financial calendar

Annual General Meeting 2023	2023-06-07
Interim report Q2 2023	2023-08-25
Interim report Q3 2023	2023-10-27
Year-end report 2023	2024-02-23

The Board of Directors and the CEO hereby certify that the interim report gives a true and fair view of the Company's operations and financial position.

Gothenburg, May 2, 2023

Toleranzia AB (publ)

Ann-Charlotte Rosendahl Chairman of the Board	Charlotte Fribert Chief Executive Officer	Thomas Eldered Member of the Board
Maarten Kraan Member of the Board	Eva Lindgren Member of the Board	Jan Mattsson Member of the Board
Kristian Sandberg Member of the Board	Anders Waas Member of the Board	

The English version of the quarterly report is an internal translation. In case of any discrepancies, the Swedish text applies.

For further information, please contact

Charlotte Fribert, VD	Phone: +46 763 19 98 98	Email: charlotte.fribert@toleranzia.com
Torbjörn Sannerstedt, CFO	Phone: +46 708 66 22 55	Email: torbjorn.sannerstedt@toleranzia.com

INCOME STATEMENT

(KSEK)	2023-01-01	2022-01-01	2022-01-01
	2023-03-31	2022-03-31	2022-12-31
	3 months	3 months	12 months
Net sales	-	-	-
Own work capitalised	10 132	8 079	35 257
Other operating income	47	21	111
	10 179	8 100	35 368
<i>Costs</i>			
Other external expenses	- 10 809	- 9 131	- 38 956
Employee benefit expenses	- 1 353	- 1 037	- 5 034
Depreciation/amortisation and impairment of property, plant and equipment and intangible fixed assets	- 6	- 4	- 17
Operating profit/loss	- 1 989	- 2 072	- 8 639
<i>Financial items</i>			
Financial income	47	-	202
Finance costs	- 5	-	- 19
Profit/loss after financial items	- 1 947	- 2 072	- 8 456
Profit/loss before tax	- 1 947	- 2 072	- 8 456
Profit/loss for the period	- 1 947	- 2 072	- 8 456

BALANCE SHEET

(KSEK)	2023-03-31	2022-03-31	2022-12-31
ASSETS			
Non-current assets			
<i>Intangible non-current assets</i>			
Capitalised expenditure for development and similar	99 998	62 849	89 866
Patent	68	68	68
	100 066	62 917	89 934
<i>Tangible non-current assets</i>			
Equipment, tools, fixtures and fittings	85	57	91
	85	57	91
Total non-current assets	100 151	62 974	90 025
Current assets			
<i>Receivables</i>			
Accounts receivable	-	-	-
Tax receivables	151	74	122
Other receivables	745	2 280	1 126
Prepaid expenses and accrued income	437	403	352
	1 333	2 757	1 600
Cash and bank balances	21 600	65 804	33 937
Total current assets	22 933	68 561	35 537
TOTAL ASSETS	123 084	131 535	125 562
(KSEK)	2023-03-31	2022-03-31	2022-12-31
EQUITY AND LIABILITIES			
<i>Equity</i>			
<i>Restricted equity</i>			
Share capital	13 789	13 789	13 789
Development expenditure fund	98 174	61 025	88 042
	111 963	74 814	101 831
<i>Unrestricted equity</i>			
Share premium fund	153 770	153 770	153 770
Retained earnings	- 146 224	- 100 620	- 127 636
Profit/loss for the period	- 1 947	- 2 072	- 8 456
	5 599	51 078	17 678
Total equity	117 562	125 892	119 509
<i>Non-current liabilities</i>			
Other non-current liabilities	850	850	850
	850	850	850
<i>Current liabilities</i>			
Trade payables	3 197	3 638	3 963
Other current liabilities	90	73	146
Accrued expenses and deferred income	1 385	1 082	1 164
	4 672	4 793	5 273
TOTAL EQUITY AND LIABILITIES	123 084	131 535	125 632

CHANGE IN EQUITY

2023-01-01 - 2023-03-31 (KSEK)	Share capital	Development expenditure fund	Share premium fond	Retained earnings	Profit/loss for the year
Opening balance, 1 January 2023	13 789	88 042	153 770	- 127 636	- 8 456
Transfer of profit/loss from previous year	-	-	-	- 8 456	8 456
Internal equity transfers	-	10 132	-	- 10 132	-
Profit/loss for the period	-	-	-	-	1 947
Closing balance, 31 March 2023	13 789	98 174	153 770	- 146 224	- 1 947

2022-01-01 - 2022-03-31 (KSEK)	Share capital	Development expenditure fund	Share premium fond	Retained earnings	Profit/loss for the year
Opening balance, 1 January 2022	13 789	52 947	153 770	- 86 292	- 6 249
Transfer of profit/loss from previous year	-	-	-	- 6 249	6 249
Internal equity transfers	-	8 079	-	- 8 079	-
Profit/loss for the period	-	-	-	-	2 072
Closing balance, 31 March 2022	13 789	61 026	153 770	- 100 620	- 2 072

2022-04-01 - 2022-12-31 (KSEK)	Share capital	Development expenditure fund	Share premium fond	Retained earnings	Profit/loss for the year
Opening balance, 1 April 2022	13 789	61 026	153 770	- 100 620	- 2 072
Issue of exercised share options	-	27 016	-	- 27 016	-
Profit/loss for the period	-	-	-	-	6 384
Closing balance, 31 December 2022	13 789	88 042	153 770	- 127 636	- 8 456

CASH FLOW STATEMENT

(KSEK)	2023-01-01	2022-01-01	2022-01-01
	2023-03-31	2022-03-31	2022-12-31
	3 months	3 months	12 months
Cash flow from operating activities			
Operating profit/loss after financial items	- 1 947	- 2 072	- 8 456
<i>Adjustment for non-cash items</i>			
Depreciation/amortisation and impairments	6	4	17
Cash flow from operating activities before changes in working capital	- 1 941	- 2 068	- 8 439
<i>Cash flow from changes in working capital</i>			
Increase (-)/decrease (+) in operating receivables	337	- 1 706	- 619
Increase (+)/decrease (-) in operating liabilities	- 601	1 379	1 858
Cash flow from operating activities	- 2 205	- 2 395	- 7 200
Cash flow from investing activities			
Investments in intangible non-current assets	- 10 132	- 8 079	- 35 095
Investments in tangible non-current assets	-	-	46
Cash flow from investing activities	- 10 132	- 8 079	- 35 141
Cash flow from financing activities			
Cash flow from financing activities	-	-	-
Cash flow for the period	- 12 337	- 10 474	- 42 341
Cash and cash equivalents at beginning of period	33 937	76 278	76 278
Cash and cash equivalents at end of period	21 600	65 804	33 937

General

Toleranzia AB (publ), Corp. Id. No 556877-2866 is a Company registered in Sweden and domiciled in Gothenburg, with address Arvid Wallgrens backe 20, 413 46 Gothenburg, Sweden.

All amounts are stated in KSEK unless stated otherwise. Amounts in brackets refer to the comparative year.

Principles for accounting and reporting

The interim report has been prepared in accordance with the Swedish Annual Accounts Act and the Swedish Accounting Standards Board's general guidelines BFNAR 2012:1 on annual financial statements and consolidated financial statements (K3).

The cash flow statement is prepared using the indirect method. The reported cash flow includes only transactions involving receipts or payments.

In addition to cash and cash equivalents, the Company classifies as cash and cash equivalents available deposits with banks and other credit institutions and short-term liquid investments that are quoted in a marketplace and have a maturity of less than three months from the date of acquisition.

Otherwise, reference is made to the accounting policies set out in the 2021 Annual Report and applicable to the Company.

Earnings per share

	2023-01-01 2023-03-31 3 months	2022-01-01 2022-03-31 3 months	2022-01-01 2022-12-31 12 months
Earnings per share, basic SEK	- 0,02	- 0,02	- 0,08
Performance measures used in the calculation of earnings per share			
Profit (loss) attributable to Company shareholders, SEK	- 1 947	- 2 072	- 8 456
Number			
Number of shares at the end of the period	110 315 231	110 315 231	110 315 231
Average number of shares	110 315 231	110 315 231	110 315 231

Related party transactions

Purchased services

(KSEK)	2023-01-01 2023-03-31 3 months	2022-01-01 2022-03-31 3 months	2022-01-01 2022-12-31 12 months
NorthX Biologics Matfors AB	470	-	370
Total	470	-	370



Company information

Organization number: 556877-2866

Legal form: Public limited company

Administrative address:

Erik Dahlbergsgatan 11 A

411 26 Göteborg

Visiting address

Arvid Wallgrens backe 20, 8 stairs

413 46 Göteborg

Website

www.toleranzia.se

E-mail:

info@toleranzia.com

Telephone:

0763-19 98 98