



Year End Report 2022

Toleranzia AB (publ) | 556877-2866



Year End Report Toleranzia AB

Fourth quarter 2022

Fourth quarter, 1 October – 31 December

- Net sales amounted to -- KSEK (--)
- Profit after financial items amounted to KSEK -2,181 thousand (-1,758)
- Cash flow from operating activities amounted to KSEK -507 (-4,079)
- Investments in intangible assets amounted to KSEK 13,090 thousand (5,753)
- Earnings per share amounted to SEK -0.02 (-0.02)

Twelve months, 1 January – 31 December

- Net sales amounted to -- KSEK (--)
- Profit after financial items amounted to KSEK -8,639 (-62852)
- Cash flow from operating activities amounted to KSEK -7,196 (-6,850)
- Investments in intangible assets amounted to KSEK 35,096 (26,314)
- Earnings per share amounted to SEK -0.08 (-0.06)

"Company" or "Toleranzia" relates to Toleranzia AB with Swedish registration number 556877-2866.

Significant events during the fourth quarter 2022

- Toleranzia entered into an agreement with Charles River Laboratories to conduct a GLP toxicology study of TOL2, the company's drug candidate for the autoimmune disease myasthenia gravis.
- Toleranzia and 3P Pharmaceuticals, the company's contract manufacturing partner, successfully manufactured the first pilot batch of TOL2 with all process steps completed on a large scale.
- Flerie Invest announced a mandatory bid to the shareholders of Toleranzia, which Toleranzia's Board of Directors recommended the shareholders of Toleranzia not to accept.

Significant events after the reporting period

- Toleranzia announced the composition of the Nomination Committee for the 2023 Annual General Meeting.

Key financial data

	2022-10-01	2021-10-01	2022-01-01	2021-01-01
	2022-12-31	2021-12-31	2022-12-31	2021-12-31
	3 months	3 months	12 months	12 months
Net sales KSEK	-	-	-	-
Operating profit/loss KSEK	- 2 181	- 1 757	- 8 639	- 6 282
Profit/loss for the period KSEK	- 2 046	- 1 726	- 8 456	- 6 249
Total assets KSEK	125 632	132 230	125 632	132 230
Cash flow for the period KSEK	- 13 646	- 9 832	- 42 341	33 127
Cash and bank balances KSEK	33 937	76 278	33 937	76 278
Equity KSEK	119 509	127 965	119 509	127 965
Earnings per share SEK	- 0,02	- 0,02	- 0,08	- 0,06
Equity/assets ratio (%)	95,1	96,8	95,1	96,8
Number of shares at the end of the period (no.)	110 315 231	110 315 231	110 315 231	110 315 231
Average number of shares (no.)	110 315 231	110 315 231	110 315 231	70 350 922
Number of employees and consultants	9	6	8	6

Comments from the CEO

Several important advances in the development of TOL2



2022 ended with an intense quarter in which we successfully produced a large-scale pilot batch of TOL2 while completing the procurement of a partner for the conduct of our upcoming GLP toxicology study. It is satisfying to sum up the year's successes while looking forward to 2023 where we expect an even faster pace.

Large-scale process yields large amounts of TOL2

At the end of 2022, we reached a very important milestone when we succeeded in producing a pilot batch of TOL2 at 1000 L scale at our contract manufacturer 3P Biopharmaceuticals (3P) in Pamplona, Spain. The production resulted in a much higher yield of pure TOL2 than we had dared to hope for and the material in the pilot batch is now being further validated. We will soon begin the next stage of the process where two more large-scale batches of TOL2 will be produced. First a technical batch for the regulatory GLP toxicology study, then a GMP batch for the clinical trial in patients.

Key partnership launched

Just before the turn of the year, after a thorough evaluation, we were able to select Charles River Laboratories (CRL) as our partner in the conduct of the GLP toxicology study of TOL2. CRL is a well-established global contract research organisation with both expertise and experience in the study of biological drug candidates with immunomodulatory properties such as TOL2. They therefore have all the systems and methods needed for the documentation of TOL2's safety profile. The results of the GLP toxicology study will form a key part of Toleranzia's application to conduct a clinical trial in patients with myasthenia gravis.

Good market prospects for a truly disease-modifying therapy like TOL2

During the year, we have seen an ever-increasing international interest in TOL2. Several partnership dialogues intensified after our preclinical data became visible thanks to the fact that Toleranzia, together with our partners at the Hellenic Pasteur Institute in Greece, both published the results in a scientific journal during the summer and presented them at the largest international conference on myasthenia gravis. The hallmark of TOL2 is that we see a clear differentiation from existing therapies both in terms of safety and magnitude and long-term impact on therapeutic efficacy in our preclinical model. Based on our preclinical results, we hope to offer a breakthrough, truly disease-modifying treatment for patients suffering from the often severe effects of myasthenia gravis as opposed to currently approved therapies, all of which are only symptom relieving.

Focus on the final pieces of the puzzle for our first clinical trial

In addition to making significant progress in production, we have also worked during the year to evaluate biomarkers for clinical efficacy, select study sites and design an optimal study design for the upcoming TOL2 clinical trial to deliver high quality data.

As we look ahead, we have several value-enhancing milestones in sight. The next step is the production of the technical batch followed by the GLP toxicology study. In parallel, we will complete the production of a GMP batch and apply for approval to conduct our first clinical trial. As the trial will be conducted directly in patients, it will allow us to demonstrate, already in a first study, not only the safety of TOL2 but also the treatment effect. We are now working to leverage the progress we have made in 2022 to achieve our goal of starting to evaluate TOL2 in patients for the first time.

Gothenburg, February 24, 2023

Charlotte Fribert

Chief Executive Officer

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 shareholdings

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. The Company has no shareholdings.

Financial development and position

The period October – December 2022

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

Other income amounted to 39 KSEK (112) during the period and consists of currency exchange rate gains.

Operating expenses for the Company amounted to 15,471 KSEK (7,622) during the period, of which 1,388 KSEK (1,095) is costs for personnel.

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 last year, as a result of the increase in the number of human resources compared to previous quarters.

Of the total cost 13,251 KSEK (5,752) relates to development of the Company product portfolio within myasthenia gravis and ANCA vasculitis and the costs incurred are capitalized on an ongoing basis as own-account work.

Operating profit/loss during the period amounted to 2,181 KSEK (1,758).

The period January – December 2022

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

Other income amounted to 111 KSEK (578) during the period and consists of currency exchange rate gains, together with contributions from Vinnova.

Operating expenses for the Company amounted to 44,007 KSEK (33,976) during the period, of which 5,034 KSEK (4,149) is costs for personnel.

In 2022, the company has added human resources equivalent to three positions to the organization - one protein chemist and two cell biologists.

Of the total cost 35,257 KSEK (27,116) relates to development of the Company product portfolio within myasthenia gravis and ANCA vasculitis and the costs incurred are capitalized on an ongoing basis as own-account work. Development work costs correspond to 80% (80%) of the Company's total operating expenses.

Operating profit/loss for the period amounted to -8,639 KSEK (-6,282).

Cash flow and liquidity

Cash flow from operating activities for the fourth quarter 2022 amounted to -507 KSEK (-4,079). For the period January - December 2022 cash flow from operating activities amounted to -7,196 KSEK (-6,850).

As of December 31, 2022, the cash balance amounted to 33,937 KSEK (76,278).

Investment

Total investments in intangible assets amounted to KSEK 13,090 (5,753) in the fourth quarter of 2022. Total investments in intangible assets amounted to KSEK 35,096 (26,314) for the period January - December 2022.

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

Personnel resources

Toleranzia is a development company where dedicated employees with solid experience and excellence are a prerequisite for commercial success and for achieving the company's vision. In 2022, the company recruited three new people and the company had nine full-time equivalent employees or contracted consultants as of 31 December 2022.

Financing

During the autumn of 2021, the company carried out a new share issue, raising capital and cash of SEK 69 532 thousand in total, before issue costs.

The company has a continuous focus on cash flow and has ongoing discussions with its major shareholders to ensure sustainable financing of ongoing and future development projects. The existing working capital is, in the opinion of the Board of Directors, sufficient for the current needs according to the business plan for the next five months. The Board works continuously to secure the Company's financing and believes that the Company will continue to be adequately financed.

In light of the above, the report has been prepared on a going concern basis as it is the assessment of management and the Board that there are a number of options available to obtain long-term financing.

Related party transactions

The company has related transactions concerning the purchase of administrative services from the company GU Ventures AB in Gothenburg. The services purchased 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 markets. Incoming raw materials and expertise are sourced from neither Russia nor Ukraine.

Share

Toleranzia's shares have been traded on Nasdaq First North since 15 October 2020. The number of shares in Toleranzia as of 31 December 2022 was 110,315,231. The share capital amounted to SEK 13,789,404 as 31 December 2022. The Company has one class of shares, each share having a quotient value of SEK 0.125 (0.125 SEK) and carrying equal rights to participate in the Company's assets and profits.

There are no outstanding option plans at the time of issuance of this interim report.

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

Ownership per December 31, 2022

Aktieägare	Andel av kapitalet	Andel av rösterna
FLERIE INVEST AB	47,4%	47,4%
FÖRSÄKRINGSAKTIEBOLAGET AVANZA PENSION	3,1%	3,1%
NORDNET PENSIONS FÖRSÄKRING AB	3,0%	3,0%
S & B CHRISTENSEN AB	2,0%	2,0%
BERGSTRÖM, NIKLAS TOBIAS	1,8%	1,8%
NORDEA LIVFÖRSÄKRING SVERIGE AB	1,8%	1,8%
NORDIC TENDER AB	1,4%	1,4%
KONSTRUKTIONS O FÖRSÄLJNINGSAKTIEBOLAGET	1,1%	1,1%
BERNHULT, PER	0,9%	0,9%
WARD, ANDREAS	0,8%	0,8%
OTHERS	36,8%	36,8%
Total	100,0%	100,0%

Review

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

Financial calendar

Annual Report 2022	2023-04-06
Interim Report Q1 2023	2023-05-03
Annual General Assembly 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 this interim report gives a true and balanced view of the Company's operations and financial situation.

Göteborg, 24 February 2022

Toleranzia AB (publ)

Ann-Charlotte Rosendahl Chairman of the Board	Charlotte Friberg CEO	Thomas Elderred Board member
Maarten Kraan Board member	Eva Lindgren Board member	Jan Mattsson Board member
Kristian Sandberg Board member	Anders Waas Board member	

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:

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Torbjörn Sannerstedt, CFO	Mobile: +46 708 66 22 55	Email: torbjorn.sannerstedt@toleranzia.com

Income statement

(KSEK)	2022-10-01 2022-12-31 3 months	2021-10-01 2021-12-31 3 months	2022-01-01 2022-12-31 12 months	2021-01-01 2021-12-31 12 months
Net sales	-	-	-	-
Own work capitalised	13 251	5 752	35 257	27 116
Other operating income	39	112	111	578
	13 290	5 865	35 368	27 694
<i>Costs</i>				
Other external expenses	- 14 078	- 6 523	- 38 956	- 29 811
Employee benefit expenses	- 1 388	- 1 095	- 5 034	- 4 149
Depreciation/amortisation and impairment of property, plant and equipment and intangible fixed assets	- 5	- 4	- 17	- 16
Operating profit/loss	- 2 181	- 1 757	- 8 639	- 6 282
<i>Financial items</i>				
Financial income	141	40	202	68
Finance costs	- 6	- 9	- 20	- 35
Profit/loss after financial items	- 2 046	- 1 726	- 8 457	- 6 249
Profit/loss before tax	- 2 046	- 1 726	- 8 457	- 6 249
Profit/loss for the period	- 2 046	- 1 726	- 8 457	- 6 249

Balance sheet

(KSEK)	2022-12-31	2021-12-31
ASSETS		
Non-current assets		
<i>Intangible non-current assets</i>		
Capitalised expenditure for development and similar	89 866	54 772
Patent	68	68
	89 934	54 840
<i>Tangible non-current assets</i>		
Equipment, tools, fixtures and fittings	91	61
	91	61
Total non-current assets	90 025	54 901
Current assets		
<i>Receivables</i>		
Accounts receivable	70	-
Tax receivables	122	58
Other receivables	1 126	387
Prepaid expenses and accrued income	352	606
	1 670	1 051
Cash and bank balances	33 937	76 278
Total current assets	35 607	77 329
TOTAL ASSETS	125 632	132 230
(KSEK)	2022-12-31	2021-12-31
EQUITY AND LIABILITIES		
<i>Equity</i>		
<i>Restricted equity</i>		
Share capital	13 789	13 789
Share issue ongoing	-	-
Development expenditure fund	88 042	52 947
	101 831	66 736
<i>Unrestricted equity</i>		
Share premium fund	153 770	153 770
Retained earnings	- 127 636	- 86 292
Profit/loss for the period	- 8 456	- 6 249
	17 678	61 229
Total equity	119 509	127 965
<i>Non-current liabilities</i>		
Other non-current liabilities	850	850
	850	850
<i>Current liabilities</i>		
Trade payables	3 963	2 383
Other current liabilities	146	156
Accrued expenses and deferred income	1 164	876
	5 273	3 415
TOTAL EQUITY AND LIABILITIES	125 632	132 230

Statement of changes in equity

2022-01-01 - 2022-12-31 (KSEK)	Share capital	Development expenditure fund	Share premium fond	Retained earnings	Profit/loss for the year
Opening balance, 1 January 2022	13 789	52 946	153 770	- 86 292	- 6 249
Transfer of profit/loss from previous year	-	-	-	6 249	6 249
Internal equity transfers	-	35 095	-	35 095	-
Profit/loss for the period	-	-	-	-	8 456
Closing balance, 31 December 2022	13 789	88 041	153 770	- 127 636	- 8 456

2021-01-01 - 2021-12-31 (KSEK)	Share capital	Development expenditure fund	Share premium fond	Retained earnings	Profit/loss for the year
Opening balance, 1 January 2021	6 793	26 632	94 476	- 55 084	- 4 894
Issue of exercised share options	3 019	-	24 513	-	-
New share issue	3 977	-	38 023	-	-
Fund raising costs	-	-	3 241	-	-
Transfer of profit/loss from previous year	-	-	-	4 894	4 894
Internal equity transfers	-	26 314	-	26 314	-
Profit/loss for the period	-	-	-	-	6 249
Closing balance, 31 December 2021	13 789	52 946	153 771	- 86 292	- 6 249

Statement of cash flow

(KSEK)	2022-10-01 2022-12-31 3 months	2021-10-01 2021-12-31 3 months	2022-01-01 2022-12-31 12 months	2021-01-01 2021-12-31 12 months
Cash flow from operating activities				
Operating profit/loss after financial items	- 2 046	- 1 726	- 8 456	- 6 249
<i>Adjustment for non-cash items</i>				
Depreciation/amortisation and impairments	5	4	17	16
Cash flow from operating activities before changes in working capital	- 2 041	- 1 722	- 8 439	- 6 233
<i>Cash flow from changes in working capital</i>				
Increase (-)/decrease (+) in operating receivables	- 179	432	- 619	- 229
Increase (+)/decrease (-) in operating liabilities	1 710	- 2 789	1 859	- 388
Cash flow from operating activities	- 510	- 4 079	- 7 199	- 6 850
Cash flow from investing activities				
Investments in intangible non-current assets	- 13 090	- 5 753	- 35 096	- 26 314
Investments in tangible non-current assets	- 46	-	- 46	-
Cash flow from investing activities	- 13 136	- 5 753	- 35 142	- 26 314
Cash flow from financing activities				
Issue of exercised share options	-	-	-	27 532
New share issue	-	-	-	42 000
Fund raising costs	-	-	-	3 241
Cash flow from financing activities	-	-	-	66 291
Cash flow for the period	- 13 646	- 9 832	- 42 341	33 127
Cash and cash equivalents at beginning of period	47 583	86 110	76 278	43 151
Cash and cash equivalents at end of period	33 937	76 278	33 937	76 278

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

	2022-10-01 2022-12-31 3 months	2021-10-01 2021-12-31 3 months	2022-01-01 2022-12-31 12 months	2021-01-01 2021-12-31 12 months
Earnings per share, basic SEK	- 0,02	- 0,02	- 0,08	- 0,06
Performance measures used in the calculation of earnings per share				
Profit (loss) attributable to Company shareholders, SEK	- 2 046	- 1 726	- 8 456	- 6 249
Number				
Number of shares at the end of the period	110 315 231	110 315 231	110 315 231	110 315 231
Average number of shares	110 315 231	110 315 231	110 315 231	70 350 922

Related party transactions

Purchases of services

(KSEK)	2022-10-01 2022-12-31 3 months	2021-10-01 2021-12-31 3 months	2022-01-01 2022-12-31 12 months	2021-01-01 2021-12-31 12 months
GU Ventures AB	105	102	446	431
Total	105	102	446	431



Company information:

Registration number: 556811-5272

Legal form: Public listed company

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