



Interim report first quarter 2024

Toleranzia AB (publ) | 556877-2866



INTERIM REPORT FIRST QUARTER 2024 TOLERANZIA AB (PUBL)

Three months, January 1 - March 31

- Operating profit/loss amounted to KSEK -1,641 (-1,988).
- Cash flow from operating activities amounted to KSEK -3,659 (-2,205)
- Investments in intangible assets amounted to KSEK 4,687 (10,132)
- Earnings per share amounted to SEK -0,00 (-0,02)

The "Company" or "Toleranzia" refers to Toleranzia AB with organization number 56877-2866.

Significant events in the first quarter of 2024

- The pivotal GLP toxicology study of TOL2 was successfully completed and provided full support for the submission of a clinical trial application in patients with myasthenia gravis.
- The scientific advisory meeting with the German Medicines Agency Paul Ehrlich Institut was conducted and provided broad support for the company's planned initial Phase I/IIa clinical trial of TOL2.

Significant events after the reporting period

- A loan agreement of SEK 20 million was signed with the Company's main shareholder Flerie Invest AB.

Key financial data

	2024-01-01 2024-03-31 3 months	2023-01-01 2023-03-31 3 months	2023-01-01 2023-12-31 12 months
Operating profit/loss (EBIT) KSEK	- 1 641	- 1 988	- 7 891
Profit/loss for the period KSEK	- 786	- 1 947	- 7 459
Total assets KSEK	156 600	123 084	160 427
Cash flow for the period KSEK	- 8 557	- 12 337	- 15 633
Cash and bank balances KSEK	9 747	21 600	18 304
Equity KSEK	152 732	117 562	153 518
Earnings per average share SEK	- 0,00	- 0,02	- 0,06
Earnings per share at full dilution [1]	- 0,00	- 0,02	- 0,03
Equity/assets ratio (%)	97,5	95,5	95,7
Number of shares at the end of the period	197 070 875	110 315 231	197 070 875
Number of shares at full dilution [1]	197 070 875	110 315 231	283 826 519
Average number of shares (no.)	197 070 875	110 315 231	133 133 154
Number of employees and consultants	10	10	12

[1] 86,755,644 warrants converted into an equal number of shares, SEK 0.50 per share. Warrants issued September 2023, subscription period 7 - 21 October 2024.

VD HAR ORDET

2024 starts with important milestones achieved



In the first quarter of 2024, we took several major steps forward in our main project TOL2. In the GLP toxicology study, which is crucial to the project, we were able to establish in January, in a preliminary report from our contracted partner, that the drug candidate was well tolerated at the high dose tested. No adverse events were observed during either the treatment or follow-up periods following intravenous administration of the drug candidate. The positive result fully supports the further development of TOL2 and the submission of a clinical trial application in patients with myasthenia gravis. The outcome of the study means that during the quarter we took a critical step closer to the first clinical trial in patients with this autoimmune disease.

At the end of January, Toleranzia held a scientific advisory meeting with the Paul Ehrlich Institute (PEI), Germany's medical regulatory authority. In March, a generally positive final report was received from the meeting. The PEI's response means that Toleranzia has received positive feedback on the TOL2 program from the authorities in Sweden, Denmark and Germany, the three countries where the clinical trial in patients with myasthenia gravis is planned to be conducted. Like the Swedish and Danish regulatory authorities, the PEI provided broad support for the TOL2 program development plan and the planned Phase I/IIa clinical trial. In addition to valuable advice on the clinical trial, the PEI provided valuable input on the design of the clinical trial application that is currently being prepared.

In parallel, work is ongoing to scale up the formulation process to produce approximately 3,000 packs of sterile, GMP-grade lyophilized TOL2 for the upcoming clinical trials. The collaboration with the contract manufacturer, which started at the end of 2023, is progressing according to plan.

Toleranzia recently received a loan commitment of SEK 20 million through an agreement with Flerie Invest AB. The agreement, which entered into force on May 1 with a term of 12 months, was signed on market terms and runs without collateral with an interest rate amounting to a maximum of nine hundred and ninety thousand SEK.

With important milestones achieved during the period, in particular the positive result from the GLP toxicology study and the favorable regulatory interactions, we are soon ready to initiate our first clinical study of TOL2 in patients with myasthenia gravis. The loan commitment of SEK 20 million is a significant addition that reassuringly strengthens the capital base for the start of the study.

Charlotte Fribert
Executive Director
Gothenburg, May 20, 2024

OM TOLERANZIA

Verksamhet

Toleranzia AB (publ) (556877-2866) är ett svenskt bioteknikföretag som är noterat på Nasdaq First North. Bolaget utvecklar läkemedel som utnyttjar immunförsvarets egen kraft för behandling av autoimmuna orphan-sjukdomar (sällsynta sjukdomar). Läkemedlen, som riktar sig mot sjukdomsorsaken, kan lindra eller bota sjukdomen och inte, som nuvarande behandlingar, enbart minska symptomen. De har potential att bli de första långtidsverkande eller botande behandlingarna som verkar specifikt på den underliggande orsaken till den autoimmuna orphan-sjukdomen de utvecklas för. Toleranzias huvudfokus är den autoimmuna nerv- och muskelsjukdomen myastenia gravis, för vilken Bolaget utvecklar läkemedelskandidaten TOL2. Därtill arbetar Toleranzia med den autoimmuna blodkärslsjukdomen ANCA-vaskulit, för vilken Bolaget utvecklar läkemedelskandidaten TOL3. Båda sjukdomarna är så kallade orphan-sjukdomar och för båda föreligger ett stort medicinskt behov och en stor marknadspotential. För ytterligare information, besök: www.toleranzia.se.

Company structure and shareholding

Toleranzia does not have any subsidiaries. Flerie Invest AB owns more than 50% of the shares, which means that Toleranzia is a subsidiary of Flerie Invest AB. The company owns no shares.

Financial development and position

Period January - March

Other operating income amounted to SEK 230 thousand (47) during the quarter.

Operating expenses amounted to 6,559 KSEK (12,167) during the quarter, of which 1,567 KSEK (1,353) relates to personnel costs.

The costs are in line with the Company's plan and expectations linked to the long-term strategy.

Of the total cost, SEK 4,687 thousand (10,132) relates to the development of the Company's project portfolio in myasthenia gravis and ANCA vasculitis, where the costs incurred are continuously capitalized as work for own account.

The operating result amounted to SEK - 1,641 thousand (-1,988) during the quarter.

Cash flow and liquidity

Cash flow from operating activities amounted to SEK -3,659 thousand (-2,205) during the quarter.

As of March 31, the Company's cash and bank balances amounted to SEK 9,747 thousand (21,600).

Investments

Total investments in intangible assets amounted to SEK 4,687 thousand (10,132) during the quarter.

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

Human resources

Toleranzia is a development company where committed employees with solid experience and cutting-edge 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, 2024.

Funding and financing

During the period, negotiations were concluded regarding conditional loans from 2013/2014 that related to completed projects. The project support in the form of loans from VGR/Tillväxtverket was finalized through

repayment remission and simultaneous payment of accrued interest. The interest was paid during the first quarter and since then the Company has no interest-bearing liabilities.

The Board of Directors and management have a continuous focus on cash flow and work continuously to ensure long-term and sustainable financing of ongoing and planned development projects and assess that there are several possible options to secure the financing of the Company.

Related party transactions

The company has related party transactions regarding the purchase of services in process development for protein production from the company NorthX Biologics Matfors AB, which is partly owned by Flerie Invest AB and whose executive chairman of the board, Thomas Eldered, is a board member of Toleranzia. Furthermore, related companies to Björn Löwenadler (CBO), Vidar Wendel-Hansen (CMO) and Thomas Pålsson (CFO) each have agreements for consulting services. Purchased services have been made on market terms.

Shares

Toleranzia's shares are traded on Nasdaq First North Growth Market since October 15, 2020. The number of shares in Toleranzia amounted to 197 070 875 as of March 31, 2023. The share is traded with the short name TOL and with ISIN code SE0007438577. As of March 31, 2023, the share capital amounted to SEK 24 633 859. 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, earnings and votes.

In addition to the share capital, 86 755 644 warrants have been issued that give the holder the right to subscribe to the same number of shares through exercise during the period October 7 - 21, 2024, at a price of SEK 0.50 per share.

Toleranzia's website contains a list of the largest owners, which is continuously updated.

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

Review by auditor

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

Financial calendar

Annual General Meeting 2024	2024-06-19
Quarterly report 2, 2024	2024-08-23
Quarterly report 3, 2024	2024-10-24

Quarterly reports and annual reports are published on the Company's website www.toleranzia.se.

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 20, 2024
Toleranzia AB (publ)

Ann-Charlotte Rosendahl Styrelseordförande	Charlotte Fribert Verkställande direktör	Thomas Eldered Styrelseledamot
Maarten Kraan Styrelseledamot	Eva Lindgren Styrelseledamot	Jan Mattsson Styrelseledamot
Kristian Sandberg Styrelseledamot		

For further information, please contact

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This information is information that Toleranzia is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-02-23 08:50 CET.

INCOME STATEMENT

(KSEK)	2024-01-01	2023-01-01	2023-01-01
	2024-03-31	2023-03-31	2023-12-31
	3 months	3 months	12 months
Own work capitalised	4 687	10 132	50 778
Other operating income	230	47	489
	4 917	10 179	51 267
Costs			
Other external expenses	- 4 851	- 10 657	- 52 733
Employee benefit expenses	- 1 567	- 1 353	- 5 589
Depreciation/amortisation and impairment of property, plant and equipment and intangible fixed assets	- 10	- 6	- 25
Other operating expenses	- 131	- 150	- 810
Operating profit/loss	- 1 641	- 1 988	- 7 891
Financial items			
Interest income and similar income items	880	47	528
Interest expenses and similar income items	- 24	- 5	- 95
Profit/loss after financial items	- 786	- 1 947	- 7 459
Profit/loss before tax	- 786	- 1 947	- 7 459
Profit/loss for the period	- 786	- 1 947	- 7 459

BALANCE SHEET

(KSEK)	2024-03-31	2023-03-31	2023-12-31
ASSETS			
Non-current assets			
<i>Intangible non-current assets</i>			
Capitalised expenditure for development and similar	145 243	99 998	140 644
Patent	157	68	68
	145 399	100 066	140 712
<i>Tangible non-current assets</i>			
Equipment, tools, fixtures and fittings	267	85	66
	267	85	66
Total non-current assets	145 666	100 151	140 778
Current assets			
<i>Receivables</i>			
Accounts receivable	-	-	5
Tax receivables	270	151	138
Other receivables	574	745	863
Prepaid expenses and accrued income	343	437	339
	1 187	1 333	1 345
Cash and bank balances	9 747	21 600	18 304
Total current assets	10 934	22 933	19 649
TOTAL ASSETS	156 600	123 084	160 427

(KSEK)	2024-03-31	2023-03-31	2023-12-31
EQUITY AND LIABILITIES			
<i>Equity</i>			
<i>Restricted equity</i>			
Share capital	24 634	13 789	24 634
Development expenditure fund	143 507	98 174	138 819
	168 141	111 963	163 453
<i>Unrestricted equity</i>			
Share premium fund	184 394	153 770	184 394
Retained earnings	- 199 016	- 146 225	- 186 870
Profit/loss for the period	- 786	- 1 947	- 7 459
	- 15 408	5 599	-9 935
Total equity	152 732	117 562	153 518
<i>Non-current liabilities</i>			
Other non-current liabilities	-	850	850
	0	850	850
<i>Current liabilities</i>			
Trade payables	1 536	3 197	4 563
Other current liabilities	93	90	173
Accrued expenses and deferred income	2 239	1 385	1 323
	3 868	4 672	6 059
TOTAL EQUITY AND LIABILITIES	156 600	123 084	160 427

CHANGE IN EQUITY

2024-01-01 - 2024-03-31 (KSEK)	Share capital	Development expenditure fund	Share premium fond	Retained earnings	Profit/loss for the year
Opening balance, 1 January 2024	24 634	138 819	184 394	- 186 870	- 7 459
Internal equity transfers	-	4 687	-	- 4 688	-
Profit/loss for the period	-	-	-	-	786
Closing balance, 31 March 2024	24 634	143 507	184 394	- 191 558	- 8 244

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	- 146 225	- 1 947

2023-01-01 - 2023-12-31 (KSEK)	Share capital	Development expenditure fund	Share premium fond	Retained earnings	Profit/loss for the year
Opening balance, 1 January 2023	13 789	88 043	153 770	- 127 636	- 8 456
Issue of exercised share options	-	-	-	-	-
New share issue	10 844	-	32 533	-	-
Fund raising costs	-	-	- 1 910	-	-
Transfer of profit/loss from previous year	-	-	-	- 8 456	8 456
Internal equity transfers	-	50 778	-	- 50 778	-
Profit/loss for the period	-	-	-	-	7 459
Closing balance, 31 December 2023	24 634	138 820	184 394	- 186 870	- 7 459

CASH FLOW STATEMENT

(KSEK)	2024-01-01	2023-01-01	2023-01-01
	2024-03-31	2023-03-31	2023-12-31
	3 months	3 months	12 months
Cash flow from operating activities			
Operating profit/loss after financial items	- 786	- 1 947	- 7 459
<i>Adjustment for non-cash items</i>			
Depreciation etc.	- 840	6	25
Cash flow from operating activities before changes in working capital	- 1 626	- 1 940	- 7 433
<i>Cash flow from changes in working capital</i>			
Increase (-)/decrease (+) in operating receivables	158	337	325
Increase (+)/decrease (-) in operating liabilities	- 2 191	- 601	785
Cash flow from operating activities	- 3 659	- 2 205	- 6 323
Cash flow from investing activities			
Investments in intangible non-current assets	- 4 687	- 10 132	- 50 778
Investments in tangible non-current assets	- 211	-	-
Cash flow from investing activities	- 4 898	- 10 132	- 50 778
Cash flow from financing activities			
New share issue	-	-	43 378
Fund raising costs	-	-	- 1 910
Cash flow from financing activities	-	-	41 468
Cash flow for the period	- 8 557	- 12 337	- 15 633
Cash and cash equivalents at beginning of period	18 304	33 937	33 937
Cash and cash equivalents at end of period	9 747	21 600	18 304

General information

Toleranzia AB (publ), corporate identity number 556877-2866, is a company registered in Sweden with its registered office in Gothenburg and with the address Arvid Wallgrens backe 20, 413 46 Gothenburg, Sweden.

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

Accounting principles

The accounts in the interim report have been prepared in accordance with the Swedish Annual Accounts Act and the Swedish Accounting Standards Board's general advice BFNAR 2012:1 Annual Report and Consolidated Accounts (K3).

The cash flow statement is prepared using the indirect method. The reported cash flow only includes transactions that have resulted in incoming or outgoing payments.

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

In all other respects, reference is made to the accounting policies set out in the 2023 Annual Report and applicable to the Company.

Earnings per share

	2024-01-01 2024-03-31 3 months	2023-01-01 2023-03-31 3 months	2023-01-01 2023-12-31 12 months
Earnings per average share SEK	- 0,00	- 0,02	- 0,04
Performance measures used in the calculation of earnings per share			
Profit (loss) , KSEK	- 786	- 1 947	- 7 459
Number			
Number of shares at the end of the period	197 070 875	110 315 231	197 070 875
Average number of shares	197 070 875	110 315 231	133 133 154

**Bolagsinformation**

Organisationsnummer: 556877-2866

Juridisk form: Publikt aktiebolag

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