



Interim report second quarter 2024

Toleranzia AB (publ) | 556877-2866



INTERIM REPORT SECOND QUARTER 2024 TOLERANZIA AB (PUBL)

Three months, April 1 - June 30

- Operating profit/loss amounted to KSEK -1 788 (-2 490)
- Cash flow from operating activities amounted to KSEK -40 (-1 238)
- Investments in intangible assets amounted to KSEK 7 414 (19 659)
- Earnings per share amounted to SEK -0,01 (-0,02)

Six months, January 1 - June 30

- Operating profit/loss amounted to KSEK -3 429 (-4 477)
- Cash flow from operating activities amounted to KSEK -3 699 (-3 442)
- Investments in intangible assets amounted to KSEK 12 101 (29 792)
- Earnings per share amounted to SEK -0,01 (-0,04)

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





Significant events in the second quarter of 2024

- Toleranzia received a loan commitment of SEK 20 million from Flerie Invest AB
- Toleranzia successfully completed a safety study of TOL2 in blood samples from patients with myasthenia gravis

Significant events after the reporting period

- Toleranzia appointed Ann-Sofie Taube as CFO of the company on an interim basis
- Toleranzia contracted a clinical CRO for the phase I/IIa study of TOL2

Key financial data

	2024-04-01	2023-04-01	2024-01-01	2023-01-01	2023-01-01
	2024-06-30	2023-06-30	2024-06-30	2023-06-30	2023-12-31
	3 months	3 months	6 months	6 months	12 months
Operating profit/loss (EBIT) KSEK	- 1 788	- 2 490	- 3 429	- 4 477	- 7 891
Profit/loss for the period KSEK	- 1 618	- 2 503	- 2 404	- 4 450	- 7 459
Total assets KSEK	156 340 	121 959	156 340	121 959	160 427
Cash flow for the period KSEK	- 7 454	- 20 897	- 16 011	- 33 234	- 15 633
Cash and bank balances KSEK	2 293 	703	2 293	703	18 304
Equity KSEK	151 114 	115 059	151 114	115 059	153 518
Earnings per average share SEK	- 0,01	- 0,02	- 0,01	- 0,04	- 0,06
Earnings per share at full dilution [1]	- 0,01	- 0,02	- 0,01	- 0,04	- 0,03
Equity/assets ratio (%)	97 	94	97	94	96
Number of shares at the end of the period	197 070 875	110 315 231	197 070 875	110 315 231	197 070 875
Number of shares at full dilution [1]	197 070 875	110 315 231	197 070 875	110 315 231	283 826 519
Average number of shares (no.)	197 070 875	110 315 231	197 070 875	110 315 231	133 133 154
Number of employees and consultants	10	10	11	14	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.

COMMENTS FROM THE CEO

Big steps towards clinical trials



The intensive work to finalize the clinical trial application for our drug candidate TOL2 for patients with myasthenia gravis progressed during the second quarter of 2024. All preclinical studies are now completed and the data is being compiled for inclusion in the application, which is planned to be submitted to the regulatory authority in the third quarter. The study itself will be conducted as a placebo-controlled multicenter study with clinics in Sweden, Denmark and Germany. We look forward with great excitement and hope to soon be able to test the drug candidate in a patient group with great medical need.

In April, the Company strengthened the financial base for its operations through a loan commitment of SEK 20 million from our main owner, 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 SEK nine hundred and ninety thousand.

At the end of May, Toleranzia conducted a unique and important preclinical study where, in blood samples from myasthenia gravis patients exposed to TOL2, we were able to clearly show that the drug candidate did not produce any signs of inflammatory immune activation or adverse effects on blood cells at the doses tested. The study results, together with the previously conducted GLP toxicology study, provide strong support for the safety of TOL2.

The scaling up of the formulation process to produce approximately 3,000 packs of sterile, freeze-dried, GMP quality TOL2 for the upcoming clinical trials is progressing according to plan. We are currently working on contracting a partner who will be responsible for all logistics, including storage, labeling and distribution of the drug product to the various clinics in connection with the treatment of recruited patients.

Shortly after the end of the period, the Company appointed Ann-Sofie Taube as CFO on an interim basis, as our current CFO was temporarily forced to take leave from her position for health reasons. Ann-Sofie Taube has more than 30 years of experience as CFO, business controller and financial advisor in various businesses and industries, and thus has solid experience in financial management and business development.

Furthermore, a key milestone was recently reached when, after an extensive review and evaluation of a large number of potential international companies, we engaged the Uppsala-based clinical CRO Clinical Trial Consultants (CTC) to be responsible for the conduct of the upcoming multicenter study of TOL2. CTC has extensive knowledge and significant experience of the type of study that Toleranzia plans to conduct, as well as its own clinical unit where the Swedish part of the study can be conducted.

At the beginning of the third quarter, Toleranzia's warrant program TO4 will be implemented. Upon full exercise of all warrants, the Company will receive approximately SEK 43.4 million. A good outcome of the program is essential to give us maximum strength in the implementation of future clinical programs, where we have the opportunity to achieve results that can mean a paradigm shift in the treatment of autoimmune diseases.

Charlotte Fribert
Executive Director

Gothenburg, August 23, 2024

ABOUT TOLERANZIA

General information about the business

Toleranzia AB (publ) (556877-2866) is a Swedish biotechnology company listed on Nasdaq First North. The company develops drugs that harness the power of the immune system to treat rare autoimmune diseases. The drugs, which target the cause of the disease, can alleviate or cure the disease and not, like current treatments, just reduce the symptoms. They have the potential to be the first long-acting or curative treatments that act specifically on the underlying cause of the rare autoimmune disease they are developed for. 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 rare diseases where so-called orphan drugs can be developed and where there is a great medical need and a large market potential. For further information, please visit: 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 April - June

Other operating income amounted to SEK 298 thousand (2) during the quarter and consists of foreign exchange gains and project support part of development projects.

Operating expenses amounted to 9 499 KSEK (22 151) during the quarter, of which 1 789 KSEK (1 506) 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 7 414 thousand (19 659) 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 -1 788 thousand (-2 490) during the quarter.

Period January - June

Other operating income amounted to SEK 528 thousand (49) during the quarter and consists of foreign exchange gains and project support part of development projects.

Operating expenses amounted to 16 058 KSEK (34 318) during the quarter, of which 3 356 KSEK (2 858) 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 12 101 thousand (29 792) 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 -2 429 thousand (-4 477) during the half year.

Cash flow and liquidity

Cash flow from operating activities amounted to SEK -40 thousand (-1 238) during the quarter. Cash flow from operating activities amounted to SEK -3 699 thousand (-3 442) during the six months.

As of June 30, the Company's cash and bank balances amounted to SEK 2 293 thousand (703).

Investments

Total investments in intangible assets amounted to SEK 7 417 thousand (19 659) during the quarter. The corresponding investment for the period January-June amounted to SEK 12 101 thousand (29 792)

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 June 30, 2024.

Funding and financing

During the period January – June, 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.

In the fall of 2023, Toleranzia carried out a new share issue, which provided the Company with capital and cash of approximately SEK 43.4 million, before issue costs. Together with the shares, warrants (TO4) were simultaneously issued with exercise during the period October 7 - 21, 2024. At full subscription, the Company will receive an additional SEK 43.4 million.

During the second quarter of 2024, Toleranzia signed a loan agreement of SEK 20 million with the Company's main owner Flerie Invest AB. The loan commitment, which entered into force on May 1, 2024, and has a duration of 12 months, is expected to ensure that the Company will be adequately financed at least twelve months after the balance sheet date. The loan was not utilized as at June 30.

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.

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 June 30, 2024. The share is traded with the short name TOL and with ISIN code SE0007438577. As of June 0, 2024, 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

Quarterly report 3, 2024
Bokslutskommuniké 2024

2024-10-24
2025-02-21

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, August 23, 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

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

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 2024-08-23 08:30 CET.

INCOME STATEMENT

(KSEK)	2024-04-01	2023-04-01	2024-01-01	2023-01-01	2023-01-01
	2024-06-30	2023-06-30	2024-06-30	2023-06-30	2023-12-31
	3 months	3 months	6 months	6 months	12 months
Own work capitalised	7 414	19 659	12 101	29 792	50 778
Other operating income	298	2	528	49	489
	7 712	19 661	12 629	29 840	51 267
<i>Costs</i>					
Other external expenses	- 7 667	- 20 161	- 12 518	- 30 818	- 52 733
Employee benefit expenses	- 1 789	- 1 506	- 3 356	- 2 858	- 5 589
Depreciation/amortisation and impairment of property, plant and equipment and intangible fixed assets	- 17	- 6	- 27	- 13	- 25
Other operating expenses	- 27	- 478	- 158	- 628	- 810
Operating profit/loss	- 1 788	- 2 490	- 3 429	- 4 477	- 7 891
<i>Financial items</i>					
Interest income and similar income items	167	0	1 046	47	528
Interest expenses and similar income items	3	14	22	19	95
Profit/loss after financial items	- 1 618	- 2 503	- 2 404	- 4 450	- 7 459
Profit/loss before tax	- 1 618	- 2 503	- 2 404	- 4 450	- 7 459
Profit/loss for the period	- 1 618	- 2 503	- 2 404	- 4 450	- 7 459

BALANCE SHEET

(KSEK)	2024-06-30	2023-06-30	2023-12-31
ASSETS			
Non-current assets			
<i>Intangible non-current assets</i>			
Capitalised expenditure for development and similar	152 657	119 658	140 644
Patent	157	68	68
	152 813	119 726	140 712
<i>Tangible non-current assets</i>			
Equipment, tools, fixtures and fittings	250	78	66
	250	78	66
Total non-current assets	153 063	119 804	140 778
Current assets			
<i>Receivables</i>			
Accounts receivable	-	-	5
Tax receivables	39	171	138
Other receivables	344	809	863
Prepaid expenses and accrued income	601	472	339
	984	1 452	1 345
Cash and bank balances	2 293	703	18 304
Total current assets	3 277	2 155	19 649
TOTAL ASSETS	156 340	121 959	160 427

(KSEK)	2024-06-30	2023-06-30	2023-12-31
EQUITY AND LIABILITIES			
<i>Equity</i>			
<i>Restricted equity</i>			
Share capital	24 634	13 789	24 634
Development expenditure fund	150 921	117 833	138 819
	175 554	131 623	163 453
<i>Unrestricted equity</i>			
Share premium fund	184 394	153 770	184 394
Retained earnings	- 206 430	- 165 884	- 186 870
Profit/loss for the period	- 2 404	- 4 450	- 7 459
	- 24 441	-16 564	-9 935
Total equity	151 114	115 059	153 518
<i>Non-current liabilities</i>			
Other non-current liabilities	-	850	850
	0	850	850
<i>Current liabilities</i>			
Trade payables	2 844	4 333	4 563
Other current liabilities	205	169	173
Accrued expenses and deferred income	2 177	1 548	1 323
	5 226	6 051	6 059
TOTAL EQUITY AND LIABILITIES	156 340	121 959	160 427

CHANGE IN EQUITY

2024-01-01 - 2024-06-30 (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
Transfer of profit/loss from previous year	-	-	-	- 7 459	7 459
Internal equity transfers	-	12 101	-	- 12 101	-
Profit/loss for the period	-	-	-	-	2 404
Closing balance, 31 March 2024	24 634	150 920	184 394	- 206 430	- 2 404

2023-01-01 - 2023-06-30 (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)	2024-04-01	2023-04-01	2024-01-01	2023-01-01	2023-01-01
	2024-06-30	2023-06-30	2024-06-30	2023-06-30	2023-12-31
	3 months	3 months	6 months	6 months	12 months
Cash flow from operating activities					
Operating profit/loss after financial items	- 1 618	- 2 503	- 2 404	- 4 450	- 7 459
<i>Adjustment for non-cash items</i>					
Depreciation etc.	17	6	823	13	25
Cash flow from operating activities before changes in working capital	- 1 602	- 2 497	- 3 228	- 4 437	- 7 433
<i>Cash flow from changes in working capital</i>					
Increase (-)/decrease (+) in operating receivables	203	99	361	218	325
Increase (+)/decrease (-) in operating liabilities	1 359	1 358	832	777	785
Cash flow from operating activities	- 40	- 1 238	- 3 699	- 3 442	- 6 323
Cash flow from investing activities					
Investments in intangible non-current assets	- 7 414	- 19 659	- 12 101	- 29 792	- 50 778
Investments in tangible non-current assets	-	-	211	-	-
Cash flow from investing activities	- 7 414	- 19 659	- 12 312	- 29 792	- 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	- 7 453	- 20 897	- 16 011	- 33 234	- 15 633
Cash and cash equivalents at beginning of period	9 747	21 600	18 304	33 937	33 937
Cash and cash equivalents at end of period	2 294	703	2 293	703	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

	2024-04-01	2023-04-01	2024-01-01	2023-01-01	2023-01-01
	2024-06-30	2023-06-30	2024-06-30	2023-06-30	2023-12-31
	3 months	3 months	6 months	6 months	12 months
Earnings per average share SEK	- 0,01	- 0,02	- 0,01	- 0,04	- 0,04
Performance measures used in the calculation of earnings per share					
Profit (loss) , KSEK	- 1 618	- 2 503	- 2 404	- 4 450	- 7 459
Number					
Number of shares at the end of the period	197 070 875	110 315 231	197 070 875	110 315 231	197 070 875
Average number of shares	197 070 875	110 315 231	197 070 875	110 315 231	133 133 154



Company information

Organization number: 556877-2866

Legal form: Public limited company

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