



Interim report third quarter 2024

Toleranzia AB (publ) | 556877-2866



INTERIM REPORT THIRD QUARTER 2024 TOLERANZIA AB (PUBL)

Three months, July 1 - September 30

- Operating profit/loss amounted to KSEK -2 809 (-1 099).
- Cash flow from operating activities amounted to KSEK 1 931 (133)
- Investments in intangible assets amounted to KSEK 10 684 (9 792)
- Earnings per average share amounted to SEK -0,01 (-0,01)

Six months, January 1 - September 30

- Operating profit/loss amounted to KSEK -5 213 (-5 549).
- Cash flow from operating activities amounted to KSEK -1 768 (-3 310)
- Investments in intangible assets amounted to KSEK 22 996 (39 583)
- Earnings per average share amounted to SEK -0,03 (-0,05)

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

Significant events in the third quarter of 2024

- Toleranzia contracted a clinical CRO for the phase I/IIa study of TOL2
- Toleranzia appointed Ann-Sofie Taube as CFO on an interim basis
- Subscription commitments were received for the exercise of warrants of series TO4 corresponding to approximately 71.14 percent

Significant events after the reporting period

- Toleranzia submitted a clinical trial application for TOL2
- The exercise period began for warrants of series TO4

Key financial data

	2024-07-01	2023-07-01	2024-01-01	2023-01-01	2023-01-01
	2024-09-30	2023-09-30	2024-09-30	2023-09-30	2023-12-31
	3 months	3 months	9 months	9 months	12 months
Operating profit/loss (EBIT) KSEK	- 2 613	- 1 292	- 6 042	- 5 770	- 7 891
Profit/loss for the period KSEK	- 2 809	- 1 099	- 5 213	- 5 549	- 7 459
Total assets KSEK	166 464	163 996	166 464	163 996	160 427
Cash flow for the period KSEK	- 1 253	31 807	- 17 264	- 1 427	- 15 633
Cash and bank balances KSEK	1 040	32 511	1 040	32 511	18 304
Equity KSEK	148 305	155 544	148 305	155 544	153 518
Earnings per average share SEK	- 0,01	- 0,01	- 0,03	- 0,05	- 0,06
Earnings per share at full dilution [1]	- 0,01	- 0,00	- 0,02	- 0,05	- 0,03
Equity/assets ratio (%)	89	95	89	95	96
Number of shares at the end of the period	197 070 875	197 070 875	197 070 875	197 070 875	197 070 875
Number of shares at full dilution [1]	283 826 519	283 826 519	283 826 519	283 826 519	283 826 519
Average number of shares (no.)	197 070 875	114 087 216	197 070 875	111 586 376	133 133 154
Number of employees and consultants	11	11	10	11	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

Application for clinical trial with TOL2 submitted



In the third quarter of 2024, we completed the extensive clinical trial application for the use of our drug candidate TOL2 in patients with myasthenia gravis and shortly after the end of the period, on October 2, we were pleased to submit the application online via the European Medicines Agency's (EMA's) CTIS portal. In the coming quarter, the Agency will review the application before an approval decision.

The planned clinical trial, which is a placebo-controlled multicenter study with participating clinics in Sweden, Denmark and Germany, is divided into two parts. In the first part, patients with myasthenia gravis will each receive a single dose of TOL2 in gradually increasing doses. In the second part, patients will receive repeated treatment with TOL2 for just under two weeks at gradually increasing doses. The study is designed to evaluate safety and tolerability and to obtain preliminary efficacy data.

In order to strengthen Toleranzia's financial base before the start of the study, we are implementing the TO4 warrant program in October, which, if fully subscribed, can provide the Company with just over SEK 43 million before issue costs. At the end of August, we were very pleased to announce that the Company received subscription commitments from Flerie Invest AB and Zonda Partners AB as well as the Company's CEO and board members for a total value of approximately SEK 30.9 million, corresponding to 71.14 percent of the total issue proceeds. With the strong support provided by the subscription commitments, we hope, despite a tough market climate, to achieve a very good result in TO4.

During the summer, the Company appointed Ann-Sofie Taube as CFO on an interim basis, during our regular CFO's leave of absence. Ann-Sofie has more than 30 years of experience as a CFO, business controller and financial advisor in various businesses and industries with solid experience in financial management and business development.

In terms of operations, the work of scaling up the formulation process continues for the manufacture of the approximately 3000 packages of sterile, freeze-dried TOL2 of GMP quality needed for the clinical study. During the period we have successfully produced a large-scale test batch of about 700 finished freeze-dried packages that will be used, among other things, to determine the shelf life of the drug product. Further, during the period, Toleranzia has also built up the chain of resources necessary for the implementation of the multicenter study as well as for labeling, storage and distribution of the lyophilized drug product.

All in all, Toleranzia has during the quarter completed several important steps to be able to start the first study in myasthenia gravis patients with the company's potentially groundbreaking treatment, and during the last quarter of the year we look forward with excitement to the response from the EMA, regarding our clinical trial application.

Charlotte Friberg

Executive Director

Gothenburg, October 21, 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 July – September

Other operating income amounted to SEK 771 thousand (213) during the quarter and consists of foreign exchange gains and project support part of development projects.

Operating expenses amounted to SEK 14 067 thousand (11 296) during the quarter, of which SEK 1 544 thousand (1 214) 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 10 684 thousand (9 792) 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 -2 613 thousand (-1 292) during the quarter.

Period January - September

Other operating income amounted to SEK 1 298 thousand (261) during the period and consists of foreign exchange gains and project support part of development projects.

Operating expenses amounted to SEK 30 125 thousand (45 615) during the period, of which SEK 4 900 thousand (4 072) 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 22 785 thousand (39 583) 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 -6 042 thousand (-5 770) during the period.

Cash flow and liquidity

Cash flow from operating activities amounted to SEK -1 931 thousand (133) during the quarter. Cash flow from operating activities amounted to SEK -1 768 thousand (-3 310) during the nine months.

As of September 30, the Company's cash and bank balances amounted to SEK 1 042 thousand (32 511).

Investments

Total investments in intangible assets amounted to SEK 10 684 thousand (9 792) during the quarter. The corresponding investment for the period Januari-September amounted to SEK 22 785 thousand (39 583)

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 11 full-time equivalent employees or contracted consultants as of September 30, 2024.

Funding and financing

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 utilized to 7.5 MSEK as of 30 September.

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.

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 30 September, 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

Year-end report 2024 2025-02-21

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

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, October 21, 2024
Toleranzia AB (publ)

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

(KSEK)	2024-07-01	2023-07-01	2024-01-01	2023-01-01	2023-01-01
	2024-09-30	2023-09-30	2024-09-30	2023-09-30	2023-12-31
	3 months	3 months	9 months	9 months	12 months
Own work capitalised	10 684	9 792	22 785	39 583	50 778
Other operating income	771	213	1 298	261	489
	11 454	10 004	24 083	39 845	51 267
<i>Costs</i>					
Other external expenses	- 12 416	- 10 040	- 24 933	- 40 859	- 52 733
Employee benefit expenses	- 1 544	- 1 214	- 4 900	- 4 072	- 5 589
Depreciation/amortisation and impairment of property, plant and equipment and intangible fixed assets	- 17	- 6	- 44	- 19	- 25
Other operating expenses	- 91	- 37	- 249	- 665	- 810
Operating profit/loss	- 2 613	- 1 292	- 6 042	- 5 770	- 7 891
<i>Financial items</i>					
Interest income and similar income items	34	258	1 080	305	528
Interest expenses and similar income items	- 229	- 65	- 251	- 85	- 95
Profit/loss after financial items	- 2 809	- 1 099	- 5 213	- 5 549	- 7 459
Profit/loss before tax	- 2 809	- 1 099	- 5 213	- 5 549	- 7 459
Profit/loss for the period	- 2 809	- 1 099	- 5 213	- 5 549	- 7 459

BALANCE SHEET

(KSEK)	2024-09-30	2023-09-30	2023-12-31
ASSETS			
Non-current assets			
<i>Intangible non-current assets</i>			
Capitalised expenditure for development and similar	163 340	129 449	140 644
Patent	157	68	68
	163 497	129 517	140 712
<i>Tangible non-current assets</i>			
Equipment, tools, fixtures and fittings	233	72	66
	233	72	66
Total non-current assets	163 730	129 589	140 778
Current assets			
<i>Receivables</i>			
Accounts receivable	-	-	5
Tax receivables	63	192	138
Other receivables	967	943	863
Prepaid expenses and accrued income	664	761	339
	1 694	1 896	1 345
Cash and bank balances	1 040	32 511	18 304
Total current assets	2 734	34 407	19 649
TOTAL ASSETS	166 464	163 996	160 427

(KSEK)	2024-09-30	2023-09-30	2023-12-31
EQUITY AND LIABILITIES			
<i>Equity</i>			
<i>Restricted equity</i>			
Share capital	24 634	24 634	24 634
Development expenditure fund	152 724	127 625	138 819
	177 358	152 259	163 453
<i>Unrestricted equity</i>			
Share premium fund	184 394	186 304	184 394
Retained earnings	- 208 234	- 177 469	- 186 870
Profit/loss for the period	- 5 213	- 5 549	- 7 459
	- 29 053	3 286	-9 935
Total equity	148 305	155 544	153 518
<i>Non-current liabilities</i>			
Other non-current liabilities	7 500	850	850
	7 500	850	850
<i>Current liabilities</i>			
Trade payables	8 425	5 711	4 563
Other current liabilities	130	93	173
Accrued expenses and deferred income	2 104	1 798	1 323
	10 658	7 602	6 059
TOTAL EQUITY AND LIABILITIES	166 464	163 996	160 427

CHANGE IN EQUITY

2024-01-01 - 2024-09-30 (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	-	13 905	-	- 13 905	-
Profit/loss for the period	-	-	-	-	5 213
Closing balance, 31 March 2024	24 634	152 724	184 394	- 208 234	- 5 213

2023-01-01 - 2023-09-30 (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
New share issue	10 844	-	32 533	-	-
Fund raising costs	-	-	-	- 1 793	-
Transfer of profit/loss from previous year	-	-	-	- 8 456	8 456
Internal equity transfers	-	39 583	-	- 39 583	-
Profit/loss for the period	-	-	-	-	5 549
Closing balance, 31 March 2023	24 633	127 625	186 303	- 177 469	- 5 549

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)	2024-07-01	2023-07-01	2024-01-01	2023-01-01	2023-01-01
	2024-09-30	2023-09-30	2024-09-30	2023-09-30	2023-12-31
	3 months	3 months	9 months	9 months	12 months
Cash flow from operating activities					
Operating profit/loss after financial items	- 2 809	- 1 099	- 5 213	- 5 549	- 7 459
<i>Adjustment for non-cash items</i>					
Depreciation etc.	17	6	806	19	25
Cash flow from operating activities before changes in working capital	- 2 792	- 1 093	- 6 019	- 5 530	- 7 433
<i>Cash flow from changes in working capital</i>					
Increase (-)/decrease (+) in operating receivables	- 710	- 444	- 349	- 227	325
Increase (+)/decrease (-) in operating liabilities	5 432	1 671	4 600	2 448	785
Cash flow from operating activities	1 931	133	- 1 768	- 3 310	- 6 323
Cash flow from investing activities					
Investments in intangible non-current assets	- 10 684	- 9 792	- 22 785	- 39 583	- 50 778
Investments in tangible non-current assets	-	-	211	-	-
Cash flow from investing activities	- 10 684	- 9 792	- 22 996	- 39 583	- 50 778
Cash flow from financing activities					
New share issue	-	43 259	-	43 259	43 378
Upptagna lån	7 500	-	7 500	-	-
Fund raising costs	-	- 1 793	-	- 1 793	- 1 910
Cash flow from financing activities	7 500	41 466	7 500	41 466	41 468
Cash flow for the period	- 1 253	31 807	- 17 264	- 1 427	- 15 633
Cash and cash equivalents at beginning of period	2 293	703	18 304	33 937	33 937
Cash and cash equivalents at end of period	1 041	32 511	1 040	32 511	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

	2024-07-01	2023-07-01	2024-01-01	2023-01-01	2023-01-01
	2024-09-30	2023-09-30	2024-09-30	2023-09-30	2023-12-31
	3 months	3 months	9 months	9 months	12 months
Earnings per average share SEK	- 0,01	- 0,01	- 0,03	- 0,05	- 0,06
Performance measures used in the calculation of earnings per share					
Profit (loss) , KSEK	- 2 809	- 1 099	- 5 213	- 5 549	- 7 459
Number					
Number of shares at the end of the period	197 070 875	197 070 875	197 070 875	197 070 875	197 070 875
Number of shares at full dilution	283 826 519	283 826 519	283 826 519	283 826 519	283 826 519
Average number of shares	197 070 875	114 087 216	197 070 875	111 586 376	133 133 154



Company information

Organization number: 556877-2866

Legal form: Public limited company

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