# toleranzia

## Year End Report 2024

Toleranzia AB (publ) | 556877-2866

## YEAR END REPORT 2024TOLERANZIA AB (PUBL)

#### Three months, October 1 – December 31

- Operating profit/loss amounted to KSEK -4 206 (-2 122).
- Cash flow from operating activities amounted to KSEK -8 513 (-2 895)
- Investments in intangible assets amounted to KSEK 7 242 (11 195)
- Earnings per average share amounted to SEK -0,02 (-0,01)

#### Twelve months, January 1 – December 31

- Operating profit/loss amounted to KSEK -10 248 (-7 891).
- Cash flow from operating activities amounted to KSEK -10 281 (-6 323)
- Investments in intangible assets amounted to KSEK 30 026 (50 778)
- Earnings per average share amounted to SEK -0,04 (-0,06)

#### Significant events in the fourth quarter of 2024

- A clinical trial application for the drug candidate TOL2 was submitted to the EMA
- The Company received approximately SEK 37 million through the warrants of series TO4
- A new Certified Adviser was appointed (Svensk Kapitalmarknadsgranskning AB)
- The composition of the Nomination Committee for the 2025 Annual General Meeting was announced

#### Significant events after the reporting period

- Toleranzia updated on the process for the Company's clinical trial application
- The clinical trial application for TOL2 was approved in Sweden and Germany

#### Key financial data

	2024-10-01	2023-10-01	2024-01-01	2023-01-01
	2024-12-31	2023-12-31	2024-12-31	2023-12-31
	3 months	3 months	12 months	12 months
Operating profit/loss (EBIT) KSEK	- 4 206	- 2 122	- 10 248	- 7891
Profit/loss for the period KSEK	- 4 224	- 1909	- 9436	- 7458
Total assets KSEK	186 474	160 427	186 474	160 427
Cash flow for the period KSEK	17 172	- 14 207	7 408	- 15 633
Cash and bank balances KSEK	13 777	18 304	13 777	18 304
Equity KSEK	180 073	153 518	180 073	153 518
Earnings per average share SEK	- 0,02	- 0,01	- 0,04	- 0,06
Equity/assets ratio (%)	89	. 95	89	95
Number of shares at the end of the period	270 962 006	197 070 875	270 962 006	197 070 875
Avarage number of shares (no.) [1]	254 095 552	133 133 154	211 404 947	133 133 154
Number of employees and consultans	10	12	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. Subscription of 73 891 131 shares was made.



### **COMMENTS FROM THE CEO**



As we conclude 2024, I am pleased to reflect on a year of significant progress and strategic milestones for Toleranzia. Our dedicated efforts have brought us closer to our goal to develop innovative life-changing therapies for patients with autoimmune diseases, with a particular focus on our lead drug candidate, TOL2, for myasthenia gravis.

#### **Important Regulatory Achievements**

In the first quarter, we achieved a pivotal milestone by successfully completing the regulatory Good Laboratory Practice (GLP) toxicology study for TOL2. The results demonstrated that TOL2 was well-tolerated at high doses, with no

adverse events observed during treatment or follow-up periods – strongly supporting its advancement into clinical development.

Building on this momentum, we engaged in a scientific advisory meeting with Germany's Paul Ehrlich Institute (PEI) in January. Their feedback was broadly supportive of our development plan and the design of our planned Phase I/IIa clinical trial. This endorsement, alongside positive feedback from regulatory authorities in Sweden and Denmark, reinforced our clinical strategy.

#### **Clinical Trial Application (CTA)**

Through the second and third quarters, we finalized the CTA for TOL2. All preclinical studies were completed, and data was compiled for submission. A key step in this process was a unique preclinical study in May, where TOL2 was exposed to blood samples from myasthenia gravis patients. The study confirmed that TOL2 did not induce inflammatory immune activation or adversely affect blood cells, further strengthening its safety profile.

In October, we took a major step forward by submitting the CTA for TOL2 to the European Medicines Agency (EMA). In February, we were delighted to announce that the CTA was approved in Sweden and Germany. The clinical trial will be a double-blind, randomized, placebo-controlled, first-in-human (FIH) Phase I/IIa trial in patients with generalized myasthenia gravis receiving single or multiple doses of increasing amounts of TOL2 to assess its safety, tolerability, and preliminary efficacy.

#### **Strengthening Our Financial Position**

To support our endeavors, we successfully completed the exercise of series TO4 warrants in October, securing approximately SEK 37 million. The high participation rate of around 85 percent underscores strong investor confidence in Toleranzia's vision and strategy. This capital provides a financial foundation as we advance into clinical development. Additional capital injections will however be required to fully fund the Phase I/IIa trial.

#### Looking Ahead

Operationally, two main areas of intensive work are underway. First, we are finalizing the formulation of the previously produced Good Manufacturing Practice (GMP) batch of drug substance into a lyophilized drug product. This work, currently ongoing with our contract manufacturing partner, will provide the necessary data for regulatory authorities to grant a final non-conditional authorization to begin the clinical trial. Second, we are dedicating significant planning efforts to ensure seamless logistics for handling, transporting, and analyzing patient samples from clinics participating in the trial.

Our focus remains steadfast on diligently initiating the TOL2 clinical trial and exploring its promising potential to transform the treatment landscape for patients with myasthenia gravis.

*Charlotte Fribert* Executive Director Gothenburg, February 21, 2025



## **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 orphan 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 orphan 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 orphan diseases for which 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 October-December**

Other operating income amounted to SEK -175 thousand (227) during the quarter and consists of foreign exchange gains and project support part of development projects.

Operating expenses amounted to SEK 11 272 thousand (13 543) during the quarter, of which SEK 1 877 thousand (1 518) 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 7 242 thousand (11 195) 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 -4 206 thousand (-2 122) during the quarter.

#### Period January - December

Other operating income amounted to SEK 1 123 thousand (489) during the period and consists of foreign exchange gains and project support part of development projects.

Operating expenses amounted to SEK 41 397 thousand (59 158) during the period, of which SEK 6 776 thousand (5 589) relates to personnel costs.

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

The cost of the Company's development work represents 73% (86%) of the total operating cost. The cost of development work related to the Company's project portfolio in myasthenia gravis and ANCA vasculitis, amounted to SEK 30 026 thousand (50 778), where the costs incurred are capitalised on an ongoing basis as own-account work.

The operating result amounted to SEK -10 248 thousand (-7 891) during the period.



#### **Cash flow and liquidity**

Cash flow from operating activities amounted to SEK -8 513 thousand (-2 895) during the quarter. Cash flow from operating activities amounted to SEK -10 281 thousand (-6 323) during the twelve months.

As of December 31, the Company's cash and bank balances amounted to SEK 13 777 thousand (18 304).

#### Investments

Total investments in intangible assets amounted to SEK 7 242 thousand (11 195) during the quarter. The corresponding investment for the period Januari-December amounted to SEK 30 026 thousand (50 778)

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 December 31, 2024.

#### Funding and financing

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.

During the second quarter of 2024, Toleranzia entered into a loan agreement of SEK 20 million with the Company's main owner, Flerie Invest AB. The loan commitment came into effect on May 1, 2024, with a term of 12 months, thereby ensuring satisfactory financing for going concern until the balance sheet date. The loan was utilized during 2024; however, as of December 31, 2024, it was not utilized in any part.

During the fourth quarter of 2024, the subscription warrants of series TO4 ("TO4"), which were issued in connection with the Company's rights issue of units in the second quarter of 2023, were exercised at approximately 85 percent. The exercised TO4 were converted into 73 891 131 new shares, providing Toleranzia with SEK 35 991 thousand after issuance costs.

The Phase I/IIa trial entails a not insignificantly increased capital requirement for the Company. Considering this, the Board of Directors is monitoring the situation and evaluating various financing options including the timing and scope of capital raising that may be beneficial to 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 270 962 006 as of 31 December, 2024. The share is traded with the short name TOL and with ISIN code SE0007438577. As of 31 December, 2024, the share capital amounted to SEK 33 870 251. 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.

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

Svensk Kapitalmarknadsgranskning AB, ca@skmg.se, is the Company's Certified Adviser.

#### **Review by auditor**

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

#### **Financial calendar**

Annual report for the financial year 2024 2025-04-30



Quarterly report 1, 2025	2025-05-06
Quarterly report 2, 2025	2025-08-20
Quarterly report 3, 2025	2025-11-11

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

#### **Annual General Meeting 2025**

The Annual General Meeting 2025 is planned to take place on June 5<sup>th</sup>, with time and place to be announced in the notice of the meeting. Publication of the annual report will take place in connection with the notice of the AGM. The annual report will be published on the Company's website <u>www.toleranzia.com</u>.

The Board of Directors does not intend to propose any dividend at the AGM 2025.

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, February 21, 2025 Toleranzia AB (publ)

Ann-Charlotte RosendahlCharlotte FribertThomas ElderedChair of the BoardCEOBoard memberMaarten KraanEva LindgrenJan MattssonBoard memberBoard memberBoard member

Kristian Sandberg Board member

The English version of the financial report is an internal translation. In case of any discrepancies, the Swedish version shall prevail.

#### For further information, please contact

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## **INCOME STATEMENT**

(KSEK)	202	4-10-01 4-12-31	202	23-10-01 23-12-31	202	24-01-01 24-12-31	202	23-01-01 23-12-31
	3	months	3	8 months	12	2 months	12	2 months
Own work capitalised		7 241		11 195		30 026		50 778
Other operating income	-	175		227		1 123		489
		7 066		11 422		31 149		51 267
Costs								
Other external expenses	-	9 237	-	11 875	-	34 170	-	52 733
Employee benefit expenses	-	1 877	-	1 518	-	6 776	-	5 589
Depreciation/amortisation and impairment of								
property, plant and equipment and intangible	-	17	-	6	-	60	-	25
fixed assets								
Other operating expenses	-	141	-	145	-	391	-	810
Operating profit/loss	-	4 206	-	2 122	-	10 248	-	7 891
Financial items								
Interest income and similar income items		93		223		1 173		528
Interest expenses and similar income items	-	111	-	10	-	361	-	95
Profit/loss after financial items	-	4 224	-	1 909	-	9 436	-	7 458
Profit/loss before tax	-	4 224	-	1 909	-	9 436	-	7 458
Profit/loss for the period	-	4 224	-	1 909	-	9 436	-	7 458

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



## **BALANCE SHEET**

(KSEK)	2024-12-31	2023-12-31
ASSETS		
Non-current assets		
Intangible non-current assets		
Capitalised expenditure for development and	170 582	140 644
similar	156	69
Patent	156 170 738	68 140 712
Tangible non gurrant accets	170738	140712
Tangible non-current assets	216	66
Equipment, tools, fixtures and fittings	216 <b>216</b>	<u> </u>
T-4-1		
Total non-current assets	170 954	140 778
Current assets		
Receivables	16	F
Accounts receivable	16	129
Tax receivables Other receivables	86 868	138
	000 773	863
Prepaid expenses and accrued income	1743	339 <b>1 345</b>
Cash and bank balances	13 777	18 304
Total current assets	15 520	19 649
TOTAL ASSETS	186 474	160 427
	2024-12-31	1900-01-00
	2024-12-31	1900-01-00
EQUITY AND LIABILITIES		
Equity		
<i>Restricted equity</i> Share capital	33 870	24 634
•	168 758	
Development expenditure fund	202 628	138 819 163 453
largetristed equits	202 020	105 455
Unrestricted equity	211 149	184 394
Share premium fund Retained earnings	- 224 267	- 186 870
Profit/loss for the period	- 9436	- 7459
	- 22 555	- 9935
Total equity	180 073	153 518
Non-current liabilities	100 075	155 510
Other non-current liabilities		850
		0.00
	0	-
Current liabilities	0	850
<i>Current liabilities</i> Trade payables	-	850
<i>Current liabilities</i> Trade payables Other current liabilities	<b>0</b> 4 285 310	<b>850</b> 4 563
Trade payables Other current liabilities	4 285	850
Trade payables	4 285 310	<b>850</b> 4 563 173



## **CHANGE IN EQUITY**

2024-01-01 - 2024-12-31	Share capital	Development expenditure fund	Share premium fond		etained arnings		fit/loss for 9 year
Opening balance, 1 January 2024	24 634	138 819	184 394	-	186 870	-	7 459
Registered new issue	9 236	-	27 709		-		-
Fund raising costs	-	-	- 954		-		-
Transfer of profit/loss from previous year	-	-	-	-	7 459		7 459
Internal equity transfers	-	29 938	-	-	29 938		-
Profit/loss for the period	-	-	-		-	-	9 436
Closing balance, 31 March 2024	33 870	168 757	211 149	-	224 267	-	9 436
2023-01-01 - 2023-12-31	Share capital	Development expenditure	Share premium	R	etained		fit/loss for

(KSEK)	Share capital	expenditure fund	premium fond		arnings		for 9 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	-	-	- 1910		-		-
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 March 2023	24 633	138 819	184 393	-	186 870	-	7 459

## **CASH FLOW STATEMENT**

(KSEK)	2024-10-01 2024-12-31		2024-10-01 2023-10-01 2024-12-31 2023-12-31			24-01-01 24-12-31	2023-01-01 2023-12-31		
	3 months		3 months		12 months		12 months		
Cash flow from operating activities									
Operating profit/loss after financial items	-	4 224	-	1 909	-	9 436	-	7 458	
Adjustment for non-cash items									
Depreciation etc.		17		6	-	790		25	
Cash flow from operating activities before changes in working capital	-	4 207	-	1 903	-	10 226	-	7 433	
Cash flow from changes in working capital									
Increase (-)/decrease (+) in operating receivables	_	49		552	-	397		325	
Increase (+)/decrease (-) in operating liabilities	_	4 257	_	1 544		343		785	
Cash flow from operating activities	-	8 513	-	2 895	-	10 280	-	6 323	
Cash flow from investing activities									
Investments in intangible non-current assets	-	7 242	-	11 195	-	30 026	-	50 778	
Investments in tangible non-current assets		-		-	-	211		-	
Cash flow from investing activities	-	7 242	-	11 195	•	30 237	-	50 778	
Cash flow from financing activities									
New share issue		36 946		-		36 946		43 378	
Fund raising costs	-	954	-	117	-	954	-	1 910	
Loans raised	-	7 500							
Cash flow from financing activities		28 492	-	117		35 992		41 468	
Cash flow for the period		12 737	-	14 207	-	4 526	-	15 633	
Cash and cash equivalents at beginning of period		1 040		32 511		18 304		33 937	
Cash and cash equivalents at end of period		13 777		18 304		13 777		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

51	2024-10-01 2024-12-31	2023-10-01 2023-12-31	2024-01-01 2024-12-31	2023-01-01 2023-12-31
	3 months	3 months	12 months	12 months
Earnings per average share SEK	- 0,02	- 0,01	- 0,04	- 0,06
Performance measures used in the calculation				
of earnings per share				
Profit (loss) , KSEK	- 4 224	- 1 909	- 9436	- 7458
Number				
Number of shares at the end of the period	270 962 006	197 070 875	270 962 006	197 070 875
Average number of shares	254 095 552	133 133 154	211 404 947	133 133 154





*Company information Organization number: 556877-2866 Legal form: Public limited company* 

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