



## Year End Report 2023

Toleranzia AB (publ) | 556877-2866



## YEAR END REPORT 2023 TOLERANZIA AB (PUBL)

### Three months, October 1 - December 31

- Operating profit/loss (EBIT) amounted to KSEK -2,121 (-2,181).
- Cash flow from operating activities amounted to KSEK -2,895 (-510).
- Investments in intangible assets amounted to KSEK 11,195 (13,089).
- Earnings per share amounted to SEK -0.01 (-0.02).

### Twelve months, January 1 – December 31

- Operating profit/loss (EBIT) amounted to KSEK -7,891 (-8,639)
- Cash flow from operating activities amounted to KSEK -6,323 (-7,199)
- Investments in intangible assets amounted to KSEK 50,778 (35,095)
- Earnings per share amounted to SEK -0.06 (-0.08)

*The "Company" or "Toleranzia" refers to Toleranzia AB with organization number 556877-2866.*

### Significant events in the fourth quarter of 2023

- Final formulation and packaging started for the drug product TOL2
- Thomas Pålsson appointed as new CFO

### Significant events after the reporting period

- The pivotal toxicology study of TOL2 provides full support for the submission of an application to initiate clinical trials in patients with myasthenia gravis
- The scientific advisory meeting with the Danish Medicines Agency, DKMA, provides broad support for the company's plans for the initial clinical phase I/IIa study of TOL2
- The Nomination Committee was presented ahead of the 2024 Annual General Meeting

### Key financial data

	2023-10-01	2022-10-01	2023-01-01	2022-01-01
	2023-12-31	2022-12-31	2023-12-31	2022-12-31
	3 months	3 months	12 months	12 months
Operating profit/loss (EBIT) KSEK	- 2 121	- 2 181	- 7 891	- 8 639
Profit/loss for the period KSEK	- 1 909	- 2 046	- 7 459	- 8 456
Total assets KSEK	160 427	125 632	160 427	125 632
Cash flow for the period KSEK	- 14 206	- 13 646	- 15 633	- 42 341
Cash and bank balances KSEK	18 304	33 937	18 304	33 937
Equity KSEK	153 518	119 509	153 518	119 509
Earnings per average share SEK	- 0,01	- 0,02	- 0,06	- 0,08
Earnings per share at full dilution [1]	- 0,01	- 0,02	- 0,03	- 0,08
Equity/assets ratio (%)	95,7	95,1	95,7	95,1
Number of shares at the end of the period	197 070 875	110 315 231	197 070 875	110 315 231
Number of shares at full dilution [1]	283 826 519	110 315 231	283 826 519	110 315 231
Average number of shares (no.)	197 070 875	110 315 231	133 133 154	110 315 231
Number of employees and consultants	12	9	12	9

[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

### Key milestones achieved towards the clinical phase



2023 has been a great year as we have taken major steps towards a new drug for patients with a severe autoimmune disease with a high unmet medical need. Several critical milestones have been reached in our lead program TOL2 - a new drug for the treatment of the neuromuscular disease myasthenia gravis.

#### **Completed production and optimized formulation**

During the year, we finalized the production of the drug substance TOL2 for the upcoming clinical study by manufacturing three large-scale batches with GMP quality. To optimize stability and facilitate handling, we developed a new freeze-dried formulation which is expected to give the final drug product a shelf life of at least two years. With these two successfully achieved milestones, we could finally, at the end of the year, initiate the formulation of all GMP batches and the production of approximately 3,000 finished drug packages that will be sent to the clinics that will conduct the clinical study.

#### **Successful tox program**

A crucial milestone for the TOL2 project was the GLP toxicology study that we conducted during the fall. The study enabled us to show that the drug candidate is well tolerated and safe to use for clinical evaluation in humans. With the positive result from the toxicology program, work was started to develop and submit a clinical trial application. Once the application is approved, the clinical phase I/IIa study can be initiated, which we hope will happen in the second half of 2024.

#### **Broad regulatory support for planned Phase I/IIa clinical study**

A detailed clinical plan was developed during the year in collaboration with leading international clinical experts. Among others, Professor James Howard from the University of North Carolina, a prominent specialist in myasthenia gravis who has been a member of the company's Scientific Advisory Board since 2021, made crucial contributions to the plan.

In a scientific advisory meeting held during the fall with the Danish Medicines Agency, DKMA, we received broad support for the quality requirements set for the drug substance TOL2, the design of the recently completed toxicology study, and the company's plans for the initial clinical phase I/IIa study. This support is highly important to us as the study will partly be conducted in Denmark. We are primarily targeting Sweden, Denmark, and Germany, where there are several clinics with a good reputation in myasthenia gravis.

#### **Research funds strengthen TOL3**

In addition to the great successes in our main project, we have also received an important research grant from Vinnova for the continued development of TOL3 where we aim to treat the autoimmune disease ANCA vasculitis. The contribution to the project, which is a collaboration between several actors, amounts to SEK 2.9 million, of which SEK 1.7 million goes to Toleranzia.

Overall, we can put a productive and successful 2023 behind us and we are now focusing on taking TOL2 into clinical studies in patients with myasthenia gravis. Our hope is that TOL2 will represent a paradigm shift in the treatment of myasthenia gravis and offer patients a specific and effective treatment that will modify the disease itself and not just relieve the symptoms as current treatments do.

*Charlotte Fribert*

Executive Director

Gothenburg, February 23, 2024

## 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](http://www.toleranzia.com).

### Company structure and shareholding

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. Nor does the company have any shareholdings in other companies.

### Financial development and position

#### The period October - December

Other operating income amounted to KSEK 227 (39) during the quarter.

The company's operating expenses amounted to KSEK 13 543 (15 471) for the quarter, of which KSEK 1 518 (1 388) 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, KSEK 11 195 (13 251) refers to the development of the Company's project portfolio in myasthenia gravis and ANCA vasculitis, where the costs incurred are capitalized on an ongoing basis as own-account work.

The operating result during the quarter amounted to KSEK - 2 121 (-2 181).

#### The period January - December

Other operating income amounted to KSEK 489 (111) during the period and consists mainly of exchange rate differences and grants from Vinnova.

The company's operating expenses amounted to KSEK 59 158 (44 007) for the period, of which KSEK 5 589 (5 034) relates to personnel costs.

The costs for the Company's development work represent 87% (81%) of the total operating expenses. The cost of development work for the Company's project portfolio in myasthenia gravis and ANCA vasculitis amounted to KSEK 50 778 (35 095). The costs are capitalized on an ongoing basis as own-account work.

The operating result for the period amounted to KSEK -7 891 (-8 639).

### Cash flow and liquidity

For the period October - December, cash flow from operating activities amounted to KSEK -2 895 (-510). For the period January - December, cash flow from operating activities amounted to KSEK -6 323 (-7 199).

As of December 31, the Company's cash and bank amounted to KSEK 18 304 (33 937).

### **Investments**

Total investments in intangible assets amounted to KSEK 11 195 (13 089) for the period October - December. Total investments in intangible fixed assets amounted to KSEK 50 778 (35 095) for the period January - December.

The investments relate to the development of the Company's project portfolio in myasthenia gravis and ANCA vasculitis and the costs are continuously capitalized as work for own account.

### **Human resources**

Toleranzia is a development company where dedicated employees with solid experience and expertise are a prerequisite for commercial success and for achieving the Company's vision. The company had 12 full-time equivalent employees or contracted consultants as of December 31, 2023.

### **Financing**

During the fall, the Company carried out a new share issue that provided the Company with capital and liquid funds of approximately SEK 43.4 million, before issue costs. Together with the shares, warrants (TO4) were issued with exercise during the period October 7 - 21, 2024, SEK 0.50 per share. Upon full subscription, the company will receive an additional SEK 43.4 million.

The company has a continuous focus on cash flow. The Board of Directors and management work continuously to ensure long-term and sustainable financing of ongoing and planned development projects and consider that there are several possible alternatives to ensure continued satisfactory financing of the Company.

In light of the above, the report has been prepared on a going concern basis.

### **Related party transactions**

The company has related transactions regarding the purchase of services in process development for protein manufacturing from the company NorthX Biologics Matfors AB, which is partly owned by Flerie Invest AB, whose executive chairman, Thomas Eldered, is a member of Toleranzia's board of directors. In addition, related companies have individual agreements for consulting services with Björn Löwenadler (CBO), Vidar Wendel-Hansen (CMO) and Thomas Pålsson (CFO). Purchased services have been provided 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 December 31, 2023. The share is traded with the short name TOL and with ISIN code SE0007438577. As of December 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.

On Toleranzia's website there is a list of the largest owners, a list that is continuously updated.

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

### **Review by the auditor**

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

**Financial calendar**

Annual report for the financial year 2023	2024-04-30
Quarterly report 1, 2024	2024-05-20
Quarterly report 2, 2024	2024-08-23
Quarterly report 3, 2024	2024-10-24

**Annual General Meeting 2024**

The Annual General Meeting 2024 is planned to take place on June 19 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 [www.toleranzia.com](http://www.toleranzia.com).

The Board of Directors does not intend to propose any dividend at the AGM 2024.

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 23, 2024

Toleranzia AB (publ)

Ann-Charlotte Rosendahl Chairman of the Board	Charlotte Fribert Chief Executive Officer	Thomas Elderred Member of the Board
Maarten Kraan Member of the Board	Eva Lindgren Member of the Board	Jan Mattsson Member of the Board

Kristian Sandberg  
Member of the Board

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**

Charlotte Fribert, VD      Phone: +46 763 19 98 98      Email: [charlotte.fribert@toleranzia.com](mailto:charlotte.fribert@toleranzia.com)

*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 08:00 CET.*

## INCOME STATEMENT

(KSEK)	2023-10-01		2022-10-01		2023-01-01		2022-01-01	
	2023-12-31		2022-12-31		2023-12-31		2022-12-31	
	3 months		3 months		12 months		12 months	
Own work capitalised	11 195		13 251		50 778		35 257	
Other operating income	227		39		489		111	
	11 422		13 290		51 267		35 368	
<i>Costs</i>								
Other external expenses	-	11 875	-	13 896	-	52 733	-	38 435
Employee benefit expenses	-	1 518	-	1 388	-	5 589	-	5 034
Depreciation/amortisation and impairment of property, plant and equipment and intangible fixed assets	-	6	-	5	-	25	-	17
Other operating expenses	-	145	-	182	-	810	-	521
Operating profit/loss	-	2 121	-	2 181	-	7 891	-	8 639
<i>Financial items</i>								
Financial income	223		141		528		202	
Finance costs	-	10	-	6	-	95	-	20
Profit/loss after financial items	-	1 909	-	2 046	-	7 459	-	8 456
Profit/loss before tax	-	1 909	-	2 046	-	7 459	-	8 456
Profit/loss for the period	-	1 909	-	2 046	-	7 459	-	8 456

## BALANCE SHEET

(KSEK)	2023-12-31	2022-12-31
<b>ASSETS</b>		
<b>Non-current assets</b>		
<i>Intangible non-current assets</i>		
Capitalised expenditure for development and similar	140 644	89 866
Patent	68	68
	<b>140 712</b>	<b>89 934</b>
<i>Tangible non-current assets</i>		
Equipment, tools, fixtures and fittings	66	91
	<b>66</b>	<b>91</b>
<b>Total non-current assets</b>	<b>140 778</b>	<b>90 025</b>
<b>Current assets</b>		
<i>Receivables</i>		
Accounts receivable	5	70
Tax receivables	138	122
Other receivables	863	1 126
Prepaid expenses and accrued income	339	352
	<b>1 345</b>	<b>1 670</b>
<b>Cash and bank balances</b>	<b>18 304</b>	<b>33 937</b>
<b>Total current assets</b>	<b>19 649</b>	<b>35 607</b>
<b>TOTAL ASSETS</b>	<b>160 427</b>	<b>125 632</b>
<b>(KSEK)</b>	<b>2023-12-31</b>	<b>2022-12-31</b>
<b>EQUITY AND LIABILITIES</b>		
<i>Equity</i>		
<i>Restricted equity</i>		
Share capital	24 634	13 789
Development expenditure fund	138 819	88 042
	<b>163 453</b>	<b>101 831</b>
<i>Unrestricted equity</i>		
Share premium fund	184 394	153 770
Retained earnings	- 186 870	- 127 636
Profit/loss for the period	- 7 459	- 8 456
	<b>- 9 935</b>	<b>17 678</b>
<b>Total equity</b>	<b>153 518</b>	<b>119 509</b>
<i>Non-current liabilities</i>		
Other non-current liabilities	850	850
	<b>850</b>	<b>850</b>
<i>Current liabilities</i>		
Trade payables	4 563	3 963
Other current liabilities	173	146
Accrued expenses and deferred income	1 323	1 164
	<b>6 059</b>	<b>5 273</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>160 427</b>	<b>125 632</b>

## CHANGE IN EQUITY

2023-01-01 - 2023-12-31 (KSEK)	Share capital	Development expenditure fund	Share premium fond	Retained earnings	Profit/loss for the year
<b>Opening balance, 1 January 2023</b>	<b>13 789</b>	<b>88 042</b>	<b>153 770</b>	<b>- 127 636</b>	<b>- 8 456</b>
Registered new 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
<b>Closing balance, 31 December 2023</b>	<b>24 634</b>	<b>138 819</b>	<b>184 394</b>	<b>- 186 870</b>	<b>- 7 459</b>

  

2022-01-01 - 2022-12-31 (KSEK)	Share capital	Development expenditure fund	Share premium fond	Retained earnings	Profit/loss for the year
<b>Opening balance, 1 January 2022</b>	<b>13 789</b>	<b>52 946</b>	<b>153 770</b>	<b>- 86 292</b>	<b>- 6 249</b>
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
<b>Closing balance, 31 December 2022</b>	<b>13 789</b>	<b>88 042</b>	<b>153 770</b>	<b>- 127 636</b>	<b>- 8 456</b>

## CASH FLOW STATEMENT

(KSEK)	2023-10-01 2023-12-31 3 months	2022-10-01 2022-12-31 3 months	2023-01-01 2023-12-31 12 months	2022-01-01 2022-12-31 12 months
<b>Cash flow from operating activities</b>				
Operating profit/loss after financial items	- 1 909	- 2 046	- 7 459	- 8 456
<i>Adjustment for non-cash items</i>				
Depreciation/amortisation and impairments	6	5	25	17
<b>Cash flow from operating activities before changes in working capital</b>	<b>- 1 903</b>	<b>- 2 041</b>	<b>- 7 433</b>	<b>- 8 440</b>
<i>Cash flow from changes in working capital</i>				
Increase (-)/decrease (+) in operating receivables	552	179	325	619
Increase (+)/decrease (-) in operating liabilities	- 1 544	1 710	785	1 859
<b>Cash flow from operating activities</b>	<b>- 2 895</b>	<b>- 510</b>	<b>- 6 323</b>	<b>- 7 199</b>
<b>Cash flow from investing activities</b>				
Investments in intangible non-current assets	- 11 195	- 13 089	- 50 778	- 35 095
Investments in tangible non-current assets	-	46	-	46
<b>Cash flow from investing activities</b>	<b>- 11 195</b>	<b>- 13 136</b>	<b>- 50 778</b>	<b>- 35 142</b>
<b>Cash flow from financing activities</b>				
New share issue	-	-	43 378	-
Fund raising costs	- 117	-	1 910	-
<b>Cash flow from financing activities</b>	<b>- 117</b>	<b>-</b>	<b>41 468</b>	<b>-</b>
<b>Cash flow for the period</b>	<b>- 14 206</b>	<b>- 13 646</b>	<b>- 15 633</b>	<b>- 42 341</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>32 511</b>	<b>47 583</b>	<b>33 937</b>	<b>76 278</b>
<b>Cash and cash equivalents at end of period</b>	<b>18 304</b>	<b>33 937</b>	<b>18 304</b>	<b>33 937</b>

## 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 2022 Annual Report and applicable to the Company.

## Earnings per share

	2023-10-01 2023-12-31 3 months		2022-10-01 2022-12-31 3 months		2023-01-01 2023-12-31 12 months		2022-01-01 2022-12-31 12 months	
Earnings per average share SEK	-	0,01	-	0,02	-	0,06	-	0,08
<b>Performance measures used in the calculation of earnings per share</b>								
Profit (loss) , KSEK	-	1 909	-	2 046	-	7 459	-	8 456
<b>Number</b>								
Number of shares at the end of the period	197 070 875		110 315 231		197 070 875		110 315 231	
Average number of shares	197 070 875		110 315 231		133 133 154		110 315 231	



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**Company information**

*Organization number: 556877-2866*

*Legal form: Public limited company*

**Address**

*Arvid Wallgrens backe 20*

*413 46 Göteborg*

**Website**

*[www.toleranza.com](http://www.toleranza.com)*

**E-mail:**

*[info@toleranza.com](mailto:info@toleranza.com)*

**Telephone:**

*0763-19 98 98*