



## **Interim report third quarter 2023**

**Toleranzia AB (publ) | 556877-2866**



## INTERIM REPORT THIRD QUARTER 2023 TOLERANZIA AB (PUBL)

### Three months, July 1 - September 30

- Net sales amounted to -- KSEK (--)
- Profit after financial items amounted to KSEK -1,099 (-2,121).
- Cash flow from operating activities amounted to KSEK 134 (-2,595).
- Investments in intangible assets amounted to KSEK 9,792 (2,350).
- Earnings per share amounted to SEK -0.01 (-0.02).

### Nine months, January 1 – September 30

- Net sales amounted to -- KSEK (--)
- Profit after financial items amounted to KSEK -5,549 (6,410)
- Cash flow from operating activities amounted to KSEK -3,309 (-6,689)
- Investments in intangible assets amounted to KSEK 39,583 (22,006)
- Earnings per share amounted to SEK -0.05 (-0.06)

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

### Significant events in the third quarter of 2023

- GMP manufacturing of TOL2 drug substance for clinical study completed
- Freeze-dried formulation of TOL2 developed
- Regulatory GLP toxicology study of TOL2 initiated
- Rights issue of units consisting of shares and warrants of series TO4 completed, which provided the Company with approximately MSEK 43.4 before issue costs

### Significant events after the reporting period

- Thomas Pålsson appointed new CFO

### Key financial data

	2023-07-01	2022-07-01	2023-01-01	2022-01-01	2022-01-01
	2023-09-30	2022-09-30	2023-09-30	2022-09-30	2022-12-31
	3 months	3 months	9 months	9 months	12 months
Net sales KSEK	-	-	-	-	-
Operating profit/loss KSEK	- 1,292	- 2,137	- 5,769	- 6,458	- 8,639
Profit/loss for the period KSEK	- 1,099	- 2,121	- 5,549	- 6,410	- 8,456
Total assets KSEK	163,996	125,968	163,996	125,968	125,632
Cash flow for the period KSEK	31,808	- 4,945	- 1,426	- 28,695	- 42,341
Cash and bank balances KSEK	32,511	47,583	32,511	47,583	33,937
Equity KSEK	155,544	121,555	155,544	121,555	119,509
Earnings per average share SEK	- 0.01	- 0.02	- 0.05	- 0.06	- 0.08
Equity/assets ratio (%)	94.8	96.5	94.8	96.5	95.1
Number of shares at the end of the period (no.)	197,070,875	110,315,231	197,070,875	110,315,231	110,315,231
Average number of shares (no.)	114,087,216	110,315,231	110,370,498	110,315,231	110,315,231
Number of employees and consultants	11	9	11	8	8

## COMMENTS FROM THE CEO

### Strong value development in the business



It is very satisfying to summarize the third quarter of the year where we have taken major steps forward in the development of the drug candidate TOL2 and strengthened the financial base for continued operations through a rights issue that raised approximately SEK 43.4 before issue costs. Not least, we have initiated the very important GLP toxicology study of TOL2 in the new freeze-dried formulation. In addition, our contract manufacturing partner has completed large-scale manufacturing of the drug substance in its GMP facility.

#### **Optimized drug formulation**

Earlier this year, we initiated a formulation development program. This included extensive testing of TOL2 in various compositions, leading to a final freeze-dried drug product with optimized storage, reconstitution and stability properties. We are currently investigating the long-term stability of the product to determine its shelf life. Our expectation is that it will be at least two years, which is very good and fully sufficient for the clinical program.

#### **Safety and tolerability evaluation**

The new formulation is now being used in the ongoing GLP toxicology study conducted at Charles River Laboratories in France. The study, which evaluates the safety and tolerability of TOL2 in a preclinical model, represents a very important part of the preclinical documentation required by regulatory authorities when we apply for authorization to initiate our first clinical study in patients with myasthenia gravis. The exposure phase has been completed and the initial observations have not indicated any unwanted effects. Further work focuses on careful examination of tissues and detailed biochemical and immunological analyses. A first preliminary report is expected shortly after the year-end.

#### **Full-scale GMP manufacturing**

In early August, we completed the full-scale GMP manufacturing of the drug substance TOL2 together with our contract manufacturing partner. The final quality analyses are now underway and, provided that all specifications are met, the manufacturing will be completed and the drug substance will be ready for final formulation, packaging and labeling into a finished pharmaceutical product with GMP quality. Thereafter, the product will be delivered continuously to the clinical centers involved in the study in patients with myasthenia gravis.

#### **Strengthened financial base**

At the end of August, we also carried out a new share issue where we successfully strengthened the cash position by approximately MSEK 43.4 before issue costs. With the improved financial base for the business, we expect to be able to complete the preclinical activities and documentation of TOL2 and take the project towards clinical studies.

Overall, we have achieved several key milestones for the TOL2 project during the quarter. We look forward with confidence to the results from the GLP toxicology study and upcoming interactions with regulatory authorities - two important milestones in the TOL2 development program as they represent the final steps before the submission of the clinical trial application. Recent progress brings us ever closer to our goal - to offer a completely new type of treatment for this rare but serious disease that currently lacks a safe, disease-specific and effective therapy.

*Charlotte Fribert*

Executive Director

Gothenburg, October 27, 2023

## 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

#### Period July - September

Net sales amounted to KSEK -- (--) during the quarter.

Other income amounted to KSEK 213 (71) during the quarter and consists of project grants from Vinnova and foreign exchange gains.

The company's operating expenses amounted to KSEK 11,297 (4,558) for the quarter, of which KSEK 1,214 (1,210) relates to personnel costs.

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

Of the total cost, KSEK 9,792 (2,350) relates 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 -1,292 (-2,137).

#### The period January – September

Net sales amounted to KSEK – (--) during the period.

Other income amounted to KSEK 261 (72) during the period and consists of project grants from Vinnova and foreign exchange gains.

Operating expenses for the Company amounted to KSEK 45,613 (28,536) during the period, of which KSEK 4,072 (3,646) are costs for personnel.

The costs for the Company's development work represent 87% (77%) of the total operating costs. The cost of development work for the Company's project portfolio in myasthenia gravis and ANCA vasculitis amounted to KSEK 39,583 (22,006). The costs incurred are capitalized on an ongoing basis as own-account work.

Operating profit/loss for the period amounted to KSEK -5,769 (-6,458).

**Cash flow and liquidity**

For the period July - September, cash flow from operating activities amounted to KSEK 134 (-2,595). For the period January – September cash flow from operating activities amounted to KSEK -3,309 (-6,689).

As of September 30, the Company's cash and bank balance amounted to KSEK 32,511 (47,583).

**Investments**

Total investments in intangible assets amounted to KSEK 9,792 (2,350) for the period July - September. Total investments in intangible assets amounted to KSEK 39,583 (22,006) for the period January - September.

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

**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 11 full-time equivalent employees or contracted consultants as of September 30, 2023.

**Financing**

During the fall, the company carried out a new share issue that provided the company with capital and liquid funds of approximately MSEK 43.4, before issue costs.

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 believe 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 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, whose executive chairman, Thomas Eldered, is a member of Toleranzia's board of directors. Purchased services have been made on market terms.

**Ongoing unrest in Europe**

There is a general uncertainty in the market caused by the ongoing conflict in Ukraine. The uncertainty has so far not affected the company's operations and is not expected to affect operations in the coming months. Toleranzia has no operations in either the Russian or Ukrainian market. Raw materials and expertise are sourced from neither Russia nor Ukraine.

**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 September 30, 2023. The share capital amounted to SEK 24,633,859, as of September 30, 2023. 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 and earnings.

There are no ongoing option programs at the time of publication of this interim report.

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

## Ownership September 30, 2023

Shareholder	Share of capital	Share of Votes
FLERIE INVEST AB	47.4%	47.4%
FÖRSÄKRINGSAKTIEBOLAGET AVANZA PENSION	3.0%	3.0%
S & B CHRISTENSEN AB	2.0%	2.0%
NORDNET PENSIONS FÖRSÄKRING AB	1.8%	1.8%
NORDEA LIVFÖRSÄKRING SVERIGE AB	1.6%	1.6%
NORDIC TENDER AB	1.4%	1.4%
KONSTRUKTION O FÖRSÄLJNINGSAKTIEBOLAGET KFAB	1.1%	1.1%
STREMP, PATRIK	1.1%	1.1%
BERGSTRÖM, NIKLAS TOBIAS	1.0%	1.0%
KAUFMANN, JOHAN	0.9%	0.9%
OTHERS	38.8%	38.8%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>

### Review by the auditor

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

### Financial calendar

Year-end report 2023 2024-02-23

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 27, 2023

Toleranzia AB (publ)

Ann-Charlotte Rosendahl Chairman of the Board	Charlotte Fribert Chief Executive Officer	Thomas Eldered Member of the Board
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Maarten Kraan Member of the Board	Eva Lindgren Member of the Board	Jan Mattsson Member of the Board
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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 2023-10-27 08:00 CEST.*

## INCOME STATEMENT

(KSEK)	2023-07-01	2022-07-01	2023-01-01	2022-01-01	2022-01-01
	2023-09-30	2022-09-30	2023-09-30	2022-09-30	2022-12-31
	3 months	3 months	9 months	9 months	12 months
Net sales	-	-	-	-	-
Own work capitalised	9,792	2,350	39,583	22,006	35,257
Other operating income	213	71	261	72	111
	<b>10,005</b>	<b>2,421</b>	<b>39,844</b>	<b>22,078</b>	<b>35,368</b>
<b>Costs</b>					
Other external expenses	- 10,077	- 3,344	- 41,522	- 24,878	- 38,956
Employee benefit expenses	- 1,214	- 1,210	- 4,072	- 3,646	- 5,034
Depreciation/amortisation and impairment of property, plant and equipment and intangible fixed assets	- 6	- 4	- 19	- 12	- 17
<b>Operating profit/loss</b>	<b>- 1,292</b>	<b>- 2,137</b>	<b>- 5,769</b>	<b>- 6,458</b>	<b>- 8,639</b>
<b>Financial items</b>					
Financial income	258	20	305	61	202
Finance costs	- 65	- 4	- 85	- 13	- 19
<b>Profit/loss after financial items</b>	<b>- 1,099</b>	<b>- 2,121</b>	<b>- 5,549</b>	<b>- 6,410</b>	<b>- 8,456</b>
<b>Profit/loss before tax</b>	<b>- 1,099</b>	<b>- 2,121</b>	<b>- 5,549</b>	<b>- 6,410</b>	<b>- 8,456</b>
<b>Profit/loss for the period</b>	<b>- 1,099</b>	<b>- 2,121</b>	<b>- 5,549</b>	<b>- 6,410</b>	<b>- 8,456</b>

## BALANCE SHEET

(KSEK)	2023-09-30	2022-09-30	2022-12-31
<b>ASSETS</b>			
<b>Non-current assets</b>			
<i>Intangible non-current assets</i>			
Capitalised expenditure for development and similar	129,449	76,777	89,866
Patent	68	68	68
	<b>129,517</b>	<b>76,845</b>	<b>89,934</b>
<i>Tangible non-current assets</i>			
Equipment, tools, fixtures and fittings	72	49	91
	<b>72</b>	<b>49</b>	<b>91</b>
<b>Total non-current assets</b>	<b>129,589</b>	<b>76,894</b>	<b>90,025</b>
<b>Current assets</b>			
<i>Receivables</i>			
Accounts receivable	-	-	70
Tax receivables	192	100	122
Other receivables	943	914	1,126
Prepaid expenses and accrued income	761	477	352
	<b>1,896</b>	<b>1,491</b>	<b>1,670</b>
<b>Cash and bank balances</b>	<b>32,511</b>	<b>47,583</b>	<b>33,937</b>
<b>Total current assets</b>	<b>34,407</b>	<b>49,074</b>	<b>35,607</b>
<b>TOTAL ASSETS</b>	<b>163,996</b>	<b>125,968</b>	<b>125,632</b>
(KSEK)	2023-09-30	2022-09-30	2022-12-31
<b>EQUITY AND LIABILITIES</b>			
<i>Equity</i>			
<i>Restricted equity</i>			
Share capital	24,634	13,789	13,789
Development expenditure fund	127,625	74,952	88,042
	<b>152,259</b>	<b>88,741</b>	<b>101,831</b>
<i>Unrestricted equity</i>			
Share premium fund	186,304	153,770	153,770
Retained earnings	- 177,470	- 114,546	- 127,636
Profit/loss for the period	- 5,549	- 6,410	- 8,456
	<b>3,285</b>	<b>32,814</b>	<b>17,678</b>
<b>Total equity</b>	<b>155,544</b>	<b>121,555</b>	<b>119,509</b>
<i>Non-current liabilities</i>			
Other non-current liabilities	850	850	850
	<b>850</b>	<b>850</b>	<b>850</b>
<i>Current liabilities</i>			
Trade payables	5,711	1,907	3,963
Other current liabilities	93	90	146
Accrued expenses and deferred income	1,798	1,566	1,164
	<b>7,602</b>	<b>3,563</b>	<b>5,273</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>163,996</b>	<b>125,968</b>	<b>125,632</b>



## CHANGE IN EQUITY

2023-01-01 - 2023-09-30 (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	10,845	-	32,534	-	-
Fund raising costs	-	-	-	1,795	-
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
<b>Closing balance, 30 September 2023</b>	<b>24,634</b>	<b>127,625</b>	<b>186,304</b>	- <b>177,470</b>	- <b>5,549</b>

2022-01-01 - 2022-09-30 (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	-	22,006	-	22,006	-
Profit/loss for the period	-	-	-	-	6,410
<b>Closing balance, 30 September 2022</b>	<b>13,789</b>	<b>74,952</b>	<b>153,770</b>	- <b>114,547</b>	- <b>6,410</b>

2022-10-01 - 2022-12-31 (KSEK)	Share capital	Development expenditure fund	Share premium fond	Retained earnings	Profit/loss for the year
<b>Opening balance, 1 October 2022</b>	<b>13,789</b>	<b>74,953</b>	<b>153,770</b>	- <b>114,547</b>	- <b>6,410</b>
Internal equity transfers	-	13,089	-	13,089	-
Profit/loss for the period	-	-	-	-	2,046
<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)	2023-07-01 2023-09-30 3 months	2022-07-01 2022-09-30 3 months	2023-01-01 2023-09-30 9 months	2022-01-01 2022-09-30 9 months	2022-01-01 2022-12-31 12 months
<b>Cash flow from operating activities</b>					
Operating profit/loss after financial items	- 1,099	- 2,121	- 5,549	- 6,410	- 8,456
<i>Adjustment for non-cash items</i>					
Depreciation/amortisation and impairments	6	4	19	12	17
<b>Cash flow from operating activities before changes in working capital</b>	- <b>1,093</b>	- <b>2,117</b>	- <b>5,530</b>	- <b>6,398</b>	- <b>8,439</b>
<i>Cash flow from changes in working capital</i>					
Increase (-)/decrease (+) in operating receivables	- 444	313	- 227	440	619
Increase (+)/decrease (-) in operating liabilities	1,671	- 791	2,448	149	1,858
<b>Cash flow from operating activities</b>	<b>134</b>	- <b>2,595</b>	- <b>3,309</b>	- <b>6,689</b>	- <b>7,200</b>
<b>Cash flow from investing activities</b>					
Investments in intangible non-current assets	- 9,792	- 2,350	- 39,583	- 22,006	- 35,095
Investments in tangible non-current assets	-	-	-	-	46
<b>Cash flow from investing activities</b>	- <b>9,792</b>	- <b>2,350</b>	- <b>39,583</b>	- <b>22,006</b>	- <b>35,141</b>
<b>Cash flow from financing activities</b>					
New share issue	43,261	-	43,261	-	-
Fund raising costs	- 1,795	-	- 1,795	-	-
<b>Cash flow from financing activities</b>	<b>41,466</b>	-	<b>41,466</b>	-	-
<b>Cash flow for the period</b>	<b>31,808</b>	- <b>4,945</b>	- <b>1,426</b>	- <b>28,695</b>	- <b>42,341</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>703</b>	<b>52,528</b>	<b>33,937</b>	<b>76,278</b>	<b>76,278</b>
<b>Cash and cash equivalents at end of period</b>	<b>32,511</b>	<b>47,583</b>	<b>32,511</b>	<b>47,583</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

	2023-07-01 2023-09-30 3 months	2022-07-01 2022-09-30 3 months	2023-01-01 2023-09-30 9 months	2022-01-01 2022-09-30 9 months	2022-01-01 2022-12-31 12 months
Earnings per average share SEK	- 0.01	- 0.02	- 0.05	- 0.06	- 0.08
<b>Performance measures used in the calculation of earnings per share</b>					
Profit (loss), KSEK	- 1,099	- 2,121	- 5,549	- 6,410	- 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	110,315,231
Average number of shares	114,087,216	110,315,231	110,370,498	110,315,231	110,315,231

## Related party transactions

### Purchased services

(KSEK)	2023-07-01 2023-09-30 3 months	2022-07-01 2022-09-30 3 months	2023-01-01 2023-09-30 9 months	2022-01-01 2022-09-30 9 months	2022-01-01 2022-12-31 12 months
NorthX Biologics Matfors AB	-	-	859	-	370
<b>Total</b>	-	-	<b>859</b>	-	<b>370</b>



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**Company information**

*Organization number: 556877-2866*

*Legal form: Public limited company*

**Address**

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