toleranzia

Annual report 2023

Org.nr. 556877-2866 | www.toleranzia.se | Arvid Wallgrens backe 20, 413 46 Göteborg

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ABOUT TOLERANZIA AB (PUBL)

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 to treat autoimmune orphan 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 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. For both diseases there is a high unmet medical need and a large market potential. Toleranzia was founded by researchers at the University of Gothenburg. The Company is based at the Biotech Center in Gothenburg. For further information, please visit: www.toleranzia.se.

ABOUT MYASTHENIA GRAVIS

In myasthenia gravis, the immune system attacks the acetylcholine receptors in the body's muscles. These receptors are proteins that relay nerve signals to the muscles. When they are attacked, the transmission of electrical impulses is disrupted, leading to severe muscle weakness. Patients' symptoms often begin insidiously, but over time a range of problems develop that severely affect patients' daily lives. They may have difficulties with chewing, swallowing, and breathing, making any kind of physical activity increasingly difficult. Reduced ability to control the muscles that regulate bowel and bladder movements is perceived as a major social handicap and, in the case of severe breathing problems, the condition can be life-threatening. Around 200,000 people in the EU and US are currently living with the disease, which mainly affects women and usually starts at the age of 20-40. The available treatments have limited efficacy and are associated with side effects that negatively affect patients' quality of life.

ABOUT ANCA VASCULITIS

ANCA vasculitis is a rare disease that occurs when the body's immune system mistakenly attacks a protein in white blood cells. This leads to the activation of the white blood cells, causing extensive inflammation of the blood vessels. This in turn can cause serious damage to the kidneys, lungs and other vital organs. Symptoms vary depending on which organs are most damaged. Patients can suffer from severe kidney failure and respiratory problems. In Europe and the United States, around 115 000 people are currently living with the disease, which, like myasthenia gravis, has no effective and safe treatment.

SUMMARY OF SELECTED FINANCIAL DATA

- Operating expenses amounted to KSEK 59 158 (44 007)
- Operating profit (EBIT) amounted to KSEK -7 891 (-8 639)
- Net result for the year amounted to KSEK -7 459 (-8 456)
- The Board will not propose a dividend

A WORD FROM THE CEO

A year of important milestones achieved in view of clinical trials

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

Finished production and optimized formulation

During the year, we have completed the large-scale production of the pharmaceutical substance TOL2 with GMP quality for the upcoming clinical study. To optimize stability and manageability, we have developed a new lyophilized formulation which is expected to give the finished drug product a shelf life of at least two years. With these two milestones successfully achieved, we were able, by the end of the year, to start the formulation of the GMP material with the aim of producing around 3,000 finished drug packages which will be distributed to the clinical centers participating in the clinical trial.

Successful tox program

A crucial milestone for the TOL2 project was the GLP toxicology study that we conducted in the fall. In the study, we showed that the drug candidate is well tolerated and safe to use for clinical evaluation in humans. With the positive result from the toxicology program, the work of preparing and submitting a clinical trial application to the European Medicines Agency is in full swing. Following approval of the application, the phase I/IIa clinical trial in myasthenia gravis can be initiated. A major advantage of conducting the first clinical trial directly in patients rather than in healthy volunteers is that, in addition to establishing the safety and tolerability of the drug candidate, it also allows us to evaluate its therapeutic efficacy.

Broad regulatory support for planned Phase I/IIa clinical trial

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 clinical specialist in myasthenia gravis who has been a member of the Company's Scientific Advisory Board since 2021, has provided crucial input to the plan.

In scientific advisory meetings held in late 2023 with the Danish Medicines Agency, DKMA, and shortly thereafter in early 2024 with the German Medicines Agency, Paul Ehrlich Institut (PEI), we received broad support for the set quality requirements for the drug substance TOL2, the design of the recently successfully completed toxicology study, as well as the Company's plans for the initial Phase I/IIa clinical trial. This support is very important to us as the study will partly be conducted in these countries. Denmark and Germany together with Sweden, which are participating countries, have many good clinics with a large patient base and good reputation in myasthenia gravis.

Research funds strengthen TOL3

In addition to the great successes in our main project, we have also received important research support from Vinnova for the further 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 our focus in 2024 is to take TOL2 into clinical trials in patients with myasthenia gravis. Our hope is that TOL2 will represent a paradigm shift in the treatment of myasthenia gravis, offering patients a specific and effective disease-modifying treatment and not just symptom relief as current treatments provide.

Charlotte Fribert
Chief Executive Officer

MANAGEMENT REPORT

The Board of Directors and the CEO of Toleranzia AB (publ), 556877-2866, hereby submit their annual report for 2023.

Information on activities

The Company is engaged in advanced drug development and aims, together with global pharmaceutical partners, to develop and commercialize drugs for the treatment of autoimmune diseases.

The Company is based in the municipality of Gothenburg, Västra Götaland County.

Company structure and shareholdings

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 own shares.

Significant events during the financial year

First quarter

- A patent application was filed to protect combination therapy with the Company's tolerogens.
- GLP production of a technical batch of TOL2 was carried out for the upcoming GLP toxicology study.
- A financial contribution of approximately SEK 1.7 million was granted by Sweden's innovation agency Vinnova within the call "Swelife and Medtech4Health - Collaborative projects for better health".

Second quarter

- Preparatory work was carried out for the upcoming GMP manufacturing and GLP toxicology study of TOL2.

Third quarter

- GMP manufacturing of TOL2 was carried out for the upcoming Phase I/IIa clinical trial.
- A freeze-drying formulation of TOL2 was developed.
- The regulatory GLP toxicology study of TOL2 was initiated.
- A rights issue of units consisting of shares and warrants of series TO4 was carried out, which provided the Company with approximately SEK 43.4 million before issue costs.

Fourth quarter

- A scientific advice meeting with the Danish Medicines Agency (DKMA) was held.
- Final formulation and packaging of TOL2 started.
- Thomas Pålsson was appointed as the new CFO.

Significant events after the end of the financial year

- A scientific advice meeting with the German Medicines Agency Paul Ehrlich Institut (PEI) was held.
- The pivotal GLP toxicology study of TOL2 was successfully completed and fully supported the submission of a clinical trial application in patients with myasthenia gravis.
- A loan agreement of SEK 20 million was signed with the Company's main shareholder Flerie Invest AB.

Turnover and results

The Company is a research and development company and had no net turnover in 2023.

Other operating income of SEK 489 (111) thousand during the period consisted mainly of currency gains, SEK 343 thousand, and grants from Vinnova, SEK 142 thousand.

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

The operating result (EBIT) for the period amounted to KSEK -7 891 (-8 639) and result for the year amounted to KSEK -7459 (-8 456).

Financial position, investments, and liquidity

Cash and cash equivalents amounted to KSEK 18,304 (33,937) and interest-bearing loans to KSEK 850 (850) as of December 31, 2023.

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 assess that there are several possible options for securing financing.

In the fall of 2023, the Company 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 Company recently signed a loan agreement of SEK 20 million with the Company's main owner Flerie Invest AB. The loan commitment, which enters 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.

Cash flow from operating activities in 2023 amounted to KSEK -6,323 (-7,199). During 2023, the Company invested KSEK 50,778 (35,095) in intangible assets (TOL2).

The equity ratio at the end of the period was 96% (95%).

Multi-year overview

Amounts in KSEK	*2023-12-31*	*2022-12-31*	*2021-12-31*	*#########*	*2019-12-31*
Profit/loss after financial items	- 7 459	- 8 456	- 6 249	- 4 894	- 7 560
Total assets	160 427	125 632	132 230	72 576	38 652
Equity/assets ratio (%)	96	95	97	94	91

Personnel

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 12 full-time equivalent employees or contracted consultants as of December 31, 2023.

The average number of employees in 2023 amounted to 7 (7).

Environmental impact

The Company does not conduct any activities requiring notification under the Environmental Code.

FUTURE DEVELOPMENTS, RISKS AND UNCERTAINTIES

Future developments

The Company's business focus is on the development of drugs for the long-acting or curative treatment of autoimmune orphan diseases. In 2024 and 2025, a major focus is on TOL2, which is being developed for the nerve-muscle disease myasthenia gravis. In parallel with this, the Company is developing another drug candidate, TOL3 for the blood vessel disease ANCA vasculitis.

Toleranzia has recently entered into a collaboration with contract manufacturer Curia (Scotland) Limited ("Curia") for the final manufacturing and packaging of the pharmaceutical product TOL2, with the aim of producing sufficient quantities of high quality suitable for the upcoming clinical trials in patients with myasthenia gravis. Under the agreement, Curia will produce approximately 3,000 finished pharmaceutical packages of sterile, freeze-dried, GMP quality TOL2. The production is based on the process for manufacturing lyophilized TOL2 with excellent stability, shelf life and handling properties, which Toleranzia developed in 2023. The finished drug packages will then be distributed to the clinical centers participating in Toleranzia's upcoming clinical trials.

The planned clinical study, which is the first to be conducted in humans, is a double-blind, multicenter, phase I/IIa study. The aim is to evaluate the safety, tolerability and immune response to ascending doses of TOL2 in patients with myasthenia gravis. As advised by regulatory authorities, 24 participants are planned to be enrolled in the study. Toleranzia has held scientific advice meetings with the Swedish Medicines Agency, the Danish Medicines Agency (DKMA) and the German Medicines Agency Paul Ehrlich Institut (PEI). All authorities have given broad support to the quality requirements set for the drug substance TOL2, the design of the recently conducted toxicology study and the planning of the clinical study.

Before a clinical trial can start, approval must be obtained from a competent authority. The preparation of a clinical trial application is currently ongoing, and submission is expected during the summer. The application includes a detailed clinical trial protocol describing the objectives, design, methodology, statistics and organization of the planned trial. The dossier has been prepared in collaboration with Toleranzia's clinical advisory board, which includes Professor James Howard, a world-leading US clinician in myasthenia gravis. In addition, Toleranzia has engaged a regulatory advisor to ensure compliance with all regulatory and ethical requirements, as well as an expert consultant to identify suitable clinical trial sites. The procurement of a clinical contract research organization, which will be responsible for parts of the implementation of the clinical trial, is in the final stages and contracting is expected to take place shortly.

Toleranzia's business model involves establishing partnerships with global pharmaceutical partners for continued clinical development and commercialization of the Company's proprietary drug candidates. Through continuous business intelligence and participation in the most important scientific conferences, the Company continues to present its technology to potential partners and ensure that the business is at the absolute forefront of the treatment of autoimmune diseases. The Company has established dialog with a number of potential partners and continues to drive business development activities towards establishing strong strategic partnerships.

The Company does not provide financial projections.

Patents and other protection

Toleranzia has commercial protection in the form of orphan designation status for the Company's drug candidate TOL2 from both the EMA in Europe and the FDA in the United States, which strengthens

Toleranzia's protection in both markets through market exclusivity. Upon commercialization, orphan drugs receive market exclusivity for 10 years in the European market and 7 years in the US market.

The Company has two pending patent applications - one to protect the manufacturing process of TOL2 and one to protect the treatment of autoimmune diseases with tolerogens in combination with other immunomodulatory agents, strengthening the Company's tolerogenic platform.

The Company also considers the prospects of establishing strong intellectual property protection for TOL3 to be good. The intention is to create both product patents and orphan drug status for TOL3 in both the EU and the US.

Financial risk

Toleranzia is a development company and therefore does not yet have any revenues and will continue to need to seek new external capital in the future. Both the size and timing of the Company's future capital requirements depend on a number of factors, including the conclusion of collaboration agreements and success in the development of products. There is a risk that new capital cannot be raised when needed or on terms acceptable to the Company. This could have a negative impact on the Company's development work, results, and financial position, which in turn could affect the Company's market value.

Operational risks

Toleranzia works continuously to identify and manage business-related risks. There are risks in all phases, both in preclinical, clinical and registration phases, which may mean that the Company's products do not result in commercial forms of treatment, which entails a risk that revenues will be completely or partially absent. The Company's risk factors are described without claiming to be comprehensive in the Company's prospectus, which was issued in connection with the rights issue in 2023 and which is available on the Company's website.

Employees

Toleranzia's key personnel, especially those in management and the Board of Directors, have extensive expertise and long experience in the Company's field of activity. Thus, the Company's future growth and success are highly dependent on the experience, knowledge and commitment of the Company's management, board of directors and other key people. The loss of one or more key individuals or difficulties in recruiting new key individuals could have negative consequences for the Company's operations and results.

Ongoing unrest in the world

There is general uncertainty in the market caused by ongoing unrest in the world. Until now, the uncertainty has not affected the Company's operations and is not expected to affect operations in the coming months.

THE SHARE

Toleranzia's shares are traded on Nasdaq First North in Stockholm with the ticker TOL. The shares have ISIN code SE0007438577 and the number of shares on December 31, 2023 was 197,070,875. The share capital amounted to SEK 24,633,859 as of December 31, 2023.

The Company has one class of shares, each share having a quota value of SEK 0.125 (SEK 0.125) and carrying equal rights to participate in the Company's assets and profits.

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

LARGEST OWNERS BY CAPITAL AND VOTES PER 2023-12-31

Flerie Invest AB	57,1%
Avanza Pension Insurance Company	3.5%
Nordnet Pensionsförsäkring AB	3%
Navcap AB	1,2%
S&B Christensen AB	1,1%

DIVIDENDS

The Board of Directors and the Managing Director propose that no dividend be paid for the financial year 2023.

EQUITY CAPITAL

Amounts in KSEK	*Share capital*	*Fund for Dev. Costs*	*Share premium*	*Retained results*	*Annual result*
Opening balance	**13 789**	**88 042**	**153 770**	**-127 636**	**-8 456**
Rights issue	10 844	-	32 533	-	-
Issue costs	-	-	- 1 910	-	-
Transfer previous year result	-	-	-	- 8 456	8 456
Transfer within equity	-	50 778	-	- 50 778	-
Profit/loss for the year	-	-	-	-	- 7 459
Closing balance	**24 634**	**138 819**	**184 394**	**-186 870**	**-7 459**

In addition to the share capital, 86,755,644 warrants have been issued that can be converted into an equal number of shares, SEK 0.50 per share, with subscription and exercise during the period October 7 - 21, 2024.

ANNUAL GENERAL MEETING

The Annual General Meeting of the Company will be held on June 19, 2024. The time and place of the Annual General Meeting will be stated in the notice, which will be published via Post & Inrikes Tidningar and on the Company's website.

The Board of Directors proposes no dividend for the year.

FINANCIAL CALENDAR

The financial calendar is updated regularly and is available on the Company's website www.toleranzia.se.

PROPOSED TREATMENT OF THE COMPANY'S PROFIT OR LOSS

The Board of Directors and the Managing Director propose that the accumulated loss, SEK 9 935 090, be dealt with as follows:

Following earnings are at the disposal of the AGM (SEK):	
Share premium fund	184 393 697
Retained earnings	-186 870 214
Net profit/loss for the year	-7 458 573
Kronor	**-9 935 090**
The Board proposes that the profits be appropriatedso that the following amount can be carried forward	-9 935 090
Kronor	**-9 935 090**

For the Company's results and position in general, please refer to the following income statements and balance sheets with accompanying notes.

INCOME STATEMENT

Amounts in KSEK	*Note*		*2022-01-01 2022-12-31*	*2021-01-01 2021-12-31*
Own work capitalized	*7,8*		50 778	35 257
Other operating income	*2*		489	111
			51 267	**35 368**
Operating expenses				
Other external expenses		-	52 733	-38 435
Personnel expenses	*3*	-	5 589	-5 034
Depreciation/Write-down of tangible and intangible assets	*7,8,9*	-	25	-17
Other operating expenses	*4*	-	810	-521
Operating profit/loss		**-**	**7 891**	**-8 639**
Profit/loss from financial items				
Interest income			528	202
Interest expenses		-	95	-20
Profit/loss after financial items		**-**	**7 459**	**-8 456**
Profit/loss before tax		**-**	**7 459**	**-8 456**
Tax on profit (loss) for the year	*6*		-	-
Profit/loss for the year		**-**	**7 459**	**-8 456**

BALANCE SHEET

Amounts in KSEK	*Note*	*2023-12-31*	*2022-12-31*
ASSETS			
Non-current assets			
Intangible assets			
Capitalized expenditure for development work	*7*	140 644	89 866
Patent	*8*	68	68
		140 712	**89 934**
Tangible assets			
Equipment, tools, fixtures and fittings	*9*	66	91
		66	**91**
Total non-current assets		**140 778**	**90 025**
Current assets			
Short term receivables			
Account receivables		5	70
Current tax receivables		138	122
Other current receivables		863	1 126
Prepayments and accrued income		339	352
		1 345	**1 670**
Liquid assets		18 304	33 937
Total current assets		**19 649**	**35 607**
TOTAL ASSETS		**160 427**	**125 632**

Amounts in KSEK	*Note*	*2023-12-31*	*2022-12-31*
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital		24 634	13 789
Fund for development expenditure		138 819	88 042
		163 453	**101 831**
Accumulated deficit			
Share premium fund		184 394	153 770
Retained earnings		-186 870	-127 636
Profit/loss for the year		-7 459	-8 456
		-9 935	**17 678**
Total equity		**153 518**	**119 509**
Non-current liabilities			
Other non-current financial liabilities	*10*	850	850
		850	**850**
Current liabilities			
Accounts payable		4 563	3 963
Other current liabilities		173	146
Accrued expenses and prepaid income	*11*	1 323	1 164
		6 059	**5 273**
TOTAL EQUITY AND LIABILITIES		**160 427**	**125 632**

CASH FLOW STATEMENT

Amounts in KSEK	*2023-01-01 2023-12-31*	*2022-01-01 2022-12-31*
The operating activities		
Result after financial items	- 7 459	- 8 456
Adjustment for items not included in the cashflow		
Depreciation	25	17
Cashflow from the operating activities before changes in working capital	**- 7 433**	**- 8 440**
Cash flow from changes in working capital		
Increase(-)/Decrease (+) in current assets	325	- 619
Increase(+)/Decrease (-) in current liabilities	785	1 859
Cashflow from the operating activities	**- 6 323**	**- 7 199**
Investment activities		
Acquisitions in intangible fixed assets	- 50 778	- 35 095
Acquisitions in tangible fixed assets	-	- 46
Cashflow from investment activities	**- 50 778**	**- 35 142**
Financing activities		
Issue of exercised warrants	-	-
New share issue	43 378	-
Fund raising costs	- 1 910	-
Cashflow from financing activities	**41 468**	**-**
This year´s cashflow	**- 15 633**	**- 42 341**
Cash and cash equivalents at the beginning of the year	**33 937**	**76 278**
Cash and cash equivalents at the end of the year	**18 304**	**33 937**

Notes to the cash flow statement

Amounts in KSEK	*2023-01-01 2023-12-31*	*2022-01-01 2022-12-31*
Interest received	528	202
Interest paid	95	20

Amounts in KSEK	*2023-12-31*	*2022-12-31*
Following sub-components are included in cash and cash equivalents:		
Bank balance	18 304	33 937
	18 304	**33 937**

Preliminary F-taxes were paid during the year in the amount of SEK 81.5 (63.5) thousand.

NOTES

Note 1 Accounting principles

Amounts in KSEK unless otherwise stated

General accounting principles

The annual report has been prepared in accordance with the Annual Accounts Act and the Swedish Accounting Standards Board's general advice BFNAR 2012:1 Annual Report and Consolidated Accounts (K3).

Accounting policies are unchanged from the previous year.

Registered office of the Company

Toleranzia AB operates as a limited company and has its registered office in Gothenburg. The head office address is Arvid Wallgrens backe 20, Gothenburg, where the Board of Directors also has its seat.

Valuation principles, etc.

Assets, provisions and liabilities have been valued at cost unless otherwise stated below.

Intangible fixed assets

Research and development expenditure

The capitalization model is applied in accounting for development expenditure. This means that expenditure incurred during the development phase is recognized as an asset when all the following conditions are met:

- It is technically feasible to complete the intangible asset so that it can be used or sold.
- The intention is to complete the intangible asset and to use or sell it.
- Conditions exist for using or selling the intangible asset.
- It is probable that the intangible asset will generate future economic benefits.
- the necessary and adequate technical, financial and other resources are available to complete the development and to use or sell the intangible asset
- The expenditure attributable to the intangible asset can be measured reliably.

Other intangible assets

Other intangible assets acquired by the entity are stated at cost less accumulated amortization and impairment losses.

Depreciation and amortization

Depreciation is calculated using the straight-line method over the estimated useful life of the asset. Depreciation is recognized as an expense in the income statement. No amortization has been made during the year. Depreciation will take place when the products are ready for commercialization.

Tangible fixed assets

Property, plant and equipment are stated at cost less accumulated depreciation and impairment losses. Cost includes the purchase price and expenditure directly attributable to the acquisition. Property, plant and equipment is recognized as an asset in the balance sheet when, on the basis of available information, it is probable that the future economic benefits associated with ownership will flow to the entity and the cost of the asset can be measured reliably.

Incremental expenditure

Subsequent expenditure is added to the cost of the asset to the extent that its performance improves

from the level at which it was originally acquired. All other subsequent expenditure is recognized as an expense in the period in which it is incurred.

Depreciation and amortization

Depreciation is provided on a straight-line basis over the estimated useful life of the asset as it reflects the expected consumption of the asset's future economic benefits. Depreciation is recognized as an expense in the income statement.

Intangible fixed assets	*Year*
Capitalized development costs	10

Tangible fixed assets	*Year*
Equipment, tools and installations	5

Impairment losses - tangible and intangible assets

At the balance sheet date, an assessment is made as to whether there is any indication that an asset's value is less than its carrying amount. If such an indication exists, the asset's recoverable amount is calculated.

The recoverable amount is the higher of an asset's fair value less costs to sell and its value in use. In calculating value in use, the present value of the future cash flows expected to arise from the use of the asset in the ordinary course of business and on disposal or retirement is estimated. The discount rate used is pre-tax and reflects market assessments of the time value of money and the risks specific to the asset. A previous impairment loss is reversed only if the reasons that led to the calculation of the recoverable amount at the time of the last impairment loss have changed.

Receivables

Receivables are recognized at the amount expected to be paid after individual assessment.

Revenues

The inflow of economic benefits that the entity has received or will receive on its own account is recognized as revenue. Revenue is measured at the fair value of the consideration received or receivable.

Foreign currency

Monetary items denominated in foreign currency are translated at the closing rate. Non-monetary items are not translated but are recorded at the exchange rate at the date of acquisition.

Public contributions

A government grant that is not conditional on future performance is recognized as revenue when the conditions for receiving the grant are met.

A government grant that is conditional on future performance is recognized as revenue when the performance takes place. If the grant has been received before the conditions for recognizing it as revenue have been met, the grant is recognized as a liability.

A government grant relating to the acquisition of a fixed asset is recognized as a reduction in the cost of the asset.

Note 2 Other operating income

Amounts in KSEK	*2023-01-01 2023-12-31*	*2022-01-01 2022-12-31*
Exchange operating rate gains on receivables/liabilities	343	101
Received grants	142	1
Other income	4	9
Total	**489**	**111**

Note 3 Employee and personnel costs

	2023-01-01 2023-12-31	*2022-01-01 2022-12-31*
Average number of employees women	3,0	3,0
Average number of employees men	4,0	4,0
Total	**7,0**	**7,0**

Note 4 Other operating expenses

	2023-01-01 2023-12-31	*2022-01-01 2022-12-31*
Exchange operating rate losses on receivables/liabilities	810	521
Total	**810**	**521**

Note 5 Operational leasing

Amounts in KSEK	*2023-01-01 2023-12-31*	*2022-01-01 2022-12-31*
Premisis rent	894	734
Total	**894**	**734**

Future years' rental costs for premises are estimated to amount to approximately SEK 986 thousand annually.

Not 6 Tax on profit (loss) for the year

Amounts in KSEK	*2023-01-01 2023-12-31*	*2022-01-01 2022-12-31*
Current tax for the year	-	-
	-	**-**

Total unutilized tax loss carryforwards amount to SEK 77.5 million on the balance sheet date.

Note 7 Capitalized expenditure for development work

Amounts in KSEK	*2023-12-31*	*2022-12-31*
Accumulated acquisition values		
-Beginning of the year	92 455	57 360
-Capitalized during the year	50 778	35 095
-Capitalization financed by contributions	- 2 589	- 2 589
Accounted values at the end of the year	**140 644**	**89 866**

The acquisition cost has been reduced by public grants received in connection with the investment.

Note 8 Patents

Amounts in KSEK	*2023-12-31*	*2022-12-31*
Accumulated acquisition values		
- Beginning of the year	2 617	2 617
-Capitalized during the year	-	-
-Capitalization financed by contributions	- 24	- 24
-Write-down	- 2 525	- 2 525
Accounted values at the end of the year	**68**	**68**

The acquisition cost has been reduced by public grants received in connection with the investment.

Note 9 Property, plant and equipment

Amounts in KSEK	*2023-12-31*	*2022-12-31*
Accumulated acquisition values		
- Beginning of the year	262	215
- New acquisitions	-	46
Accumulated depreciation		
-Beginning of the year	- 171	- 154
-This year´s depreciation	- 25	- 17
Accounted values at the end of the year	**66**	**91**

Note 10 Other long-term liabilities

Amounts in KSEK	*2023-12-31*	*2022-12-31*
Västra Götalandsregionen/Tillväxtverket	850	850
	850	**850**

The loan from the Västra Götaland Region is a conditional loan without an amortization schedule. The repayment obligation of the loan is generated by revenues linked to projects part-financed by the loan. The lender can also write off the loan if the results for which financing was sought are not achieved.

Note 11 Accrued expenses and deferred income

Amounts in KSEK	*2023-12-31*	*2022-12-31*
-Personnel costs	1 108	975
-Other interim liabilities	215	190
	1 323	**1 164**

Note 12 Pledged assets and contingent liabilities

Amounts in KSEK	*2023-12-31*	*2022-12-31*
Pledged assets and collateral, company mortgage	250	250
Contingent liabilities	None	None

Note 13 Significant events after the end of the financial year

- A scientific advice meeting with the German Medicines Agency Paul Ehrlich Institut (PEI) was held.
- The pivotal GLP toxicology study of TOL2 was successfully completed and fully supported the submission of a clinical trial application in patients with myasthenia gravis.
- A loan agreement of SEK 20 million was signed with the Company's main shareholder Flerie Invest AB.

Note 14 Definitions of key figures

Balance sheet total: Total assets
Solidity: Total equity incl. equity share of untaxed reserves / Total assets

SIGNATURES

Gothenburg on

Ann-Charlotte Rosendahl
Chairman of the Board of Directors

Charlotte Fribert
Chief Executive Officer

Thomas Eldered
Member of the Board of Directors

Maarten Kraan
Member of the Board of Directors

Eva Lindgren
Member of the Board of Directors

Jan Mattsson
Member of the Board of Directors

Kristian Sandberg
Member of the Board of Directors

Our audit report was submitted on
Ernst & Young AB

Linda Sallander
Authorized Auditor

THIS IS A TRANSLATION FROM THE SWEDISH ORIGINAL

Auditor's report

To the general meeting of the shareholders of Toleranzia AB (publ), corporate identity number 556877 - 2866

Report on the annual accounts

Opinions

We have audited the annual accounts of Toleranzia AB for the financial year 2023. The annual accounts of the company are included on pages 4-18 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of Toleranzia AB as of 31 December 2023 and the financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet.

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the *Auditor's Responsibilities* section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Other Information than the annual accounts

This document also contains other information than the annual accounts and is found on pages 2-3. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts, including the disclosures, and whether the annual accounts represent the underlying transactions and events in a manner that achieves fair presentation.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

Report on other legal and regulatory requirements

Opinions

In addition to our audit of the annual accounts, we have also audited the administration of the Board of Directors and the Managing Director of Toleranzia AB for the financial year 2023 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the *Auditor's Responsibilities* section. We are

independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Gothenburg as per the day of electronic signature

Ernst & Young AB

Linda Sallander
Authorized Public Accountant