



## Annual report 2022



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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, only reduce 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 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. For both diseases there is a great medical need and a large market potential. Toleranzia was founded by researchers at the University of Gothenburg. The company operates at the Biotech Center in Gothenburg. For further information, please visit: [www.toleranzia.se](http://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 serve as relay stations for nerve signals to the muscles. When they are attacked, the transmission of electrical impulses is disrupted, leading to severe muscle weakness. The patients' symptoms often start slowly, but over time a range of problems develop that severely affect their daily lives. They may have difficulties with chewing and swallowing and also with 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 widespread 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, among other things. Around 115,000 people in Europe and the US are currently living with the disease, which, like myasthenia gravis, has no effective and safe treatment.

## TOLERANZIA IN NUMBERS

	2022-10-01	2021-10-01	2022-01-01	2021-01-01
	2022-12-31	2021-12-31	2022-12-31	2021-12-31
	3 months	3 months	12 months	12 months
Net sales KSEK	-	-	-	-
Operating profit/loss KSEK	- 2,181	- 1,757	- 8,639	- 6,282
Profit/loss for the year KSEK	- 2,046	- 1,726	- 8,456	- 6,249
Total assets KSEK	125,632	132,230	125,632	132,230
Cash flow for the period KSEK	- 13,646	- 9,832	- 42,341	- 33,127
Liquid assets KSEK	33,937	76,278	33,937	76,278
Equity KSEK	119,509	127,965	119,509	127,965
Earnings per share SEK	- 0	- 0	- 0	- 0
Equity/assets ratio (%)	95	97	95	91
Number of shares outstanding on the balance sheet date (pcs)	110,315,231	110,315,231	110,315,231	110,315,231
Average number of shares (pcs)	110,315,231	110,315,231	110,315,231	70,350,922
Number of employees and consultants	9	4	8	4

## A WORD FROM THE CEO

### A year of great progress, which became clearly visible internationally



2022 was the year when we laid the foundation for the upcoming clinical development of our tolerance-inducing drug candidate TOL2 - we successfully scaled up the manufacturing process, published strong preclinical data, and contracted a partner for the important GLP toxicology study of the drug substance.

During the year, we participated in several conferences and partnering meetings to spread awareness of our tolerance-inducing treatment concept. In the spring, world-leading researchers gathered for the 14th edition of the Myasthenia Gravis Foundation of America's international conference. Our preclinical results for TOL2, which were presented at the conference and subsequently published in the renowned journal *Frontiers of Immunology*, attracted considerable attention. Since there are still no specific treatments that stop the disease progression, there was great interest in our treatment concept, which has the potential to completely eliminate the cause of the disease. During the fall, we participated in partnering meetings on several continents. Overall, we find that the international interest in TOL2 has increased, especially since new treatments for myasthenia gravis have achieved sales success despite the fact that they only relieve symptoms and do not, like TOL2, fully address the major medical need in the disease.

Towards the end of the year, together with our contract manufacturer, we managed to produce a pilot batch of TOL2 on an industrial scale. In an evaluation, we found that all steps not only met our high requirements, but also resulted in a higher yield of purified TOL2 than expected. During the year, we also secured access to the manufacturing material that was in short supply during the pandemic, to avoid material shortages further hampering the process. We are now continuing our collaboration with 3P to implement large-scale production of TOL2 in 2023. We recently produced a technical quality batch for the upcoming GLP toxicology study and during the summer we will produce a GMP quality batch for the upcoming clinical study in MG patients.

At the end of December, we signed an agreement with a contract research organization to conduct a GLP toxicology study on TOL2. Tolerance induction is a new field and we have a partner with the right technical and scientific competence and a proven track record of delivering high quality GLP toxicology studies. Together with them, we are now developing a process to characterize, validate and document all the analytical methods that form the basis of our toxicology and safety evaluation of TOL2.

In 2022, Toleranzia carried out large parts of the basic work to be able to deliver high-quality data in the upcoming clinical study with TOL2, by engaging leading clinical expertise, selecting study centers, evaluating biomarkers for clinical efficacy and designing an optimal study design. All in all, 2022 was an intense and productive year and 2023 will be at least as intense, with several major milestones to look forward to such as the large-scale manufacturing of TOL2 with GMP quality, the GLP toxicology study where we expect to be able to show that TOL2 is well tolerated and safe to use for clinical evaluation in humans and the subsequent application to conduct our first clinical trial in MG patients where we can obtain both safety data and information on therapeutic effect - very important steps for Toleranzia.

Gothenburg, March 31, 2023

*Charlotte Fribert*  
Executive Director

## **MANAGEMENT REPORT**

The Board of Directors and the CEO of Toleranzia AB (publ) (556877-2866) hereby submit their annual report for 2022.

### **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 shareholding**

Toleranzia has no subsidiaries and is not part of any group. Nor does it have any shareholdings.

### **Significant events during the financial year**

#### **First quarter**

- The availability of the purification material required for the production of TOL2 was secured after a pandemic-induced shortage of material.

#### **Second quarter**

- Toleranzia's results for TOL2, demonstrating therapeutic proof-of-concept in a preclinical disease model, were published in the scientific journal *Frontiers in Immunology*.
- Toleranzia's results for TOL2 were presented at The 14th MGFA International Conference on Myasthenia And Related Disorders organized every five years by the Myasthenia Gravis Foundation of America (MGFA).
- A research consortium in which Toleranzia participates as an industrial partner was supported by the the Swedish Knowledge Foundation, KKS.

#### **Third quarter**

- A collaboration was established with Dr. Amy Rosenberg, former Director of the Division of Therapeutic Proteins at the FDA, for regulatory advice.
- Torbjörn Sannerstedt was appointed as the new Chief Financial Officer (CFO).

#### **Fourth quarter**

- A pilot batch of TOL2 was produced where all process steps were carried out on a large scale.
- An agreement was reached with Charles River Laboratories to conduct a GLP toxicology study on TOL2.
- A mandatory cash offer to the shareholders of Toleranzia was announced by Flerie Invest.

### **Significant events after the end of the financial year**

- The composition of the Nomination Committee for the 2023 AGM was announced.
- A patent application was filed to protect combination therapy with the Company's tolerogens.
- A technical batch of TOL2 was produced to be used in the upcoming GLP toxicology study.
- A financial contribution of approximately SEK 1.7 million was granted by the Swedish innovation agency Vinnova within the call "Swelife and Medtech4Health - Collaborative projects for better health".

### **Turnover and results**

The company is a research and development company and had no net turnover in 2022.

Other income of KSEK 111 (578) during the period consisted of foreign exchange gains, and grants from Vinnova.

The company's operating expenses amounted to KSEK 44 007 (33 976) for the period, of which KSEK 5 034 (4 149) relates to personnel costs.

The operating result for the period amounted to KSEK -8 639 (-6 282).

### **Financial position, investments and liquidity**

The company's financial position and liquidity are satisfactory. As of December 31, 2022, cash and cash equivalents amounted to KSEK 33 937 (76 278).

Cash flow from operating activities in 2022 after changes in working capital amounted to KSEK -7 196 (-6 850). During the year, the company has had significant development costs for the drug candidate TOL2 ahead of the upcoming clinical trials.

During 2022, the company has invested KSEK 35 096 (26 314) in intangible assets and KSEK 49 (--) in tangible assets.

The equity ratio at the end of the period amounted to 95.1% (96.8%).

### **Multi-year overview**

<i>Amounts in KSEK</i>	<i>2022-12-31</i>	<i>2021-12-31</i>	<i>2020-12-31</i>	<i>2019-12-31</i>	<i>2018-12-31</i>
Net sales	-	-	-	-	-
Profit/loss after financial items	- 8,456	- 6,249	- 4,894	- 7,560	- 5,658
Total assets	125,632	132,229	72,576	38,652	30,388
Equity/assets ratio (%)	95	97	94	91	91

### **Staff**

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. During 2022, the Company recruited three new people and the Company had nine full-time equivalent employees or contracted consultants as of December 31, 2022.

The number of permanent employees at year-end amounted to 6.0 (4.0).

### **Environmental impact**

The company does not conduct any activities subject to 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-term or curative treatment of autoimmune orphan diseases. In 2023 and 2024, a major focus is on TOL2, which is under development for the neuromuscular disease myasthenia gravis. In parallel, the Company is developing another drug candidate; TOL3 for the blood vessel disease ANCA vasculitis.

The collaboration with the contract manufacturer 3P continues in 2023 as planned. 3P has recently produced larger quantities of TOL2 to enable Toleranzia to carry out the remaining toxicology, stability and formulation studies. The latter is done in collaboration with HCAB, CMC Assist AS and Bioneer AS, three companies with leading expertise in CMC and drug formulation, with a background in biologics development from NovoNordisk and others. The next milestone is that 3P will manufacture sufficient quantities of the drug substance TOL2 according to GMP for the upcoming clinical study in patients with myasthenia gravis.

Toleranzia recently entered into a collaboration with a contract research organization (CRO) to conduct the GLP toxicology study of TOL2, which is a regulatory requirement to establish TOL2's safety profile and thus lay the foundation for its use in clinical trials. The CRO is a well-established global contract research organization with solid expertise and experience in studying biological drug candidates with immunomodulatory properties such as TOL2. Toleranzia has previously conducted two important toxicology and safety studies of TOL2 - an in silico immunotoxicology study and a preliminary in vivo toxicology study in rats. Neither of these studies indicated that there would be any risk of unwanted immunogenicity in humans. The results from the GLP toxicology study will form a central part of Toleranzia's application to conduct a clinical trial in patients with myasthenia gravis.

The design of the clinical phase I/IIa study of TOL2 is ongoing. Toleranzia has previously conducted a scientific advisory meeting with the Swedish Medicines Agency, which supported the proposed development strategy and provided valuable feedback on the manufacturing of TOL2, the preclinical program and the design of the first clinical study. The company is now planning for scientific advisory meetings with the regulatory authorities in the European countries where the Phase I/IIa clinical trial is planned to take place. Before applying for a clinical trial, a clinical trial protocol must be written, describing in detail the objectives, design, methodology, statistics and organization of the planned trial. To develop this protocol, Toleranzia works with its clinical advisory board, which includes Professor James Howard, one of the leading clinicians in MG in the US. In addition to the protocol, a number of other documents are included in a clinical trial application. For these, Toleranzia engages a leading European company with a focus on product development and regulatory issues, which ensures that all regulatory and ethical requirements are identified and complied with, and an expert consultant who identifies and evaluates clinical trial sites before the final selection of these.

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 environment analysis 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 several potential partners and continues to drive business development activities towards the establishment of strong strategic partnerships.

The company does not provide financial forecasts.

## **Patents and other protection**

Toleranzia has commercial protection in the form of orphan drug designation for the Company's drug candidate TOL2 from both the EMA in Europe and the FDA in the US, which strengthens Toleranzia's protection in both markets through market exclusivity. The company also has an ongoing patent application aimed at protecting the manufacturing process for TOL2.

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

In addition, the Company has an ongoing patent application aimed at protecting the treatment of autoimmune diseases with tolerogens in combination with other immunomodulatory agents, which strengthens the Company's tolerogenic platform.

## **Financial risk**

Toleranzia is a development company and therefore has no revenues yet and will need to seek new external capital in the future. The size and timing of the Company's future capital needs 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 may have negative consequences for the Company's development work, results and financial position, which in turn may affect the Company's market value.

In the fall of 2021, the Company carried out a new share issue, through which the Company received capital and liquid funds totaling SEK 69 532 thousand, before issue costs.

The Company has a constant focus on cash flow and works continuously to secure financing. The Board and management have ongoing discussions with major shareholders and believe that there are several possible options and commitments to obtain long-term and sustainable financing of ongoing and future development projects and ensure that the Company will be satisfactorily financed at least twelve months after the balance sheet date.

## **Operational risk**

Toleranzia has a continuous process to identify and manage existing risks.

There are risks in all phases, both in the 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 are lost in whole or in part.

The Company's risk factors are described without claiming to be comprehensive in the Company's prospectus issued in connection with the rights issue in 2021 and which is available on the Company's website.

## **Ability to manage growth**

The business will grow organically in the coming years. As the business grows and the workforce increases, the Company needs to ensure that the organization has effective planning and management processes in order to implement the agreed business plan in a developing and highly competitive market. Managing growth requires investment and allocation of valuable management resources. If the Company does not manage growth effectively, this could have a negative impact on its financial performance.



## Employees

The company's future development depends on the organization's ability to retain and recruit staff with relevant experience, knowledge and commitment. The company is working to reduce dependence on key personnel through good documentation of procedures and working methods. However, there is still a risk that any person who is part of the company management, or any other key person, terminates their employment in the Company, which risks having a negative impact on the Company's operations, results and financial position.

## Ongoing unrest in Europe

There is a general uncertainty in the market caused by Russia's invasion of Ukraine. The uncertainty has so far 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 since October 15, 2020. The share has ISIN code SE0007438577 and the short name TOL. As of December 31, 2022, the number of shares in Toleranzia amounts to 110 315 231. As of December 31, 2022, the share capital amounts to SEK 13 789 404.

The Company has one class of shares, with 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](mailto:ca@mangold.se).

## THE FIVE LARGEST OWNERS BY CAPITAL AND VOTES AS OF 2022-12-31

Flerie Invest AB, 47%

The insurance company Avanza Pension, 3%.

Nordnet Pensionsförsäkring AB, 3%.

S & B Christensen AB, 2

Bergström, Niklas Tobias, 2

## DIVIDENDS

The Board of Directors and the CEO propose that no dividend be paid for the financial year 2022-01-01 - 2022-12-31.

## EQUITY CAPITAL

<i>Amounts in KSEK</i>	<i>Share capital</i>	<i>Fund for Dev. Costs</i>	<i>Share premium</i>	<i>Retained results</i>	<i>Annual result</i>
Opening balance	13,789	52,946	153,770	-86,292	-6,249
Transfer previous year result	-	-	-	6,249	6,249
Transfer within equity	-	35,095	-	35,095	-
Profit/loss for the year	-	-	-	-	8,456
<b>Closing balance</b>	<b>13,789</b>	<b>88,041</b>	<b>153,770</b>	<b>-127,636</b>	<b>-8,456</b>

## PROPOSAL FOR THE TREATMENT OF THE COMPANY'S PROFIT OR LOSS

The Board of Directors and the CEO propose that the available funds, SEK 17 677 832, be allocated as follows:

### Till årsstämman förfogande står:

Överkursfond	153 770 259
Balanserat resultat	-127 635 997
Årets resultat	-8 456 430
<b>Kronor</b>	<b>17 677 832</b>
Styrelsen föreslår att i ny räkning överförs	17 677 832
<b>Kronor</b>	<b>17 677 832</b>

Regarding the Company's results and position in general, please refer to the following income statements and balance sheets with associated supplementary information.

## ANNUAL GENERAL MEETING

The Annual General Meeting of the Company will be held on June 7, 2023, at 10.00. Notice of the Annual General Meeting will be published in Post & Inrikes Tidningar and on the Company's website.

## FINANCIAL CALENDAR

- Interim report Q1 2023 2023-05-03
- Annual General Meeting 2023 2023-06-07
- Interim report Q2 2023 2023-08-25
- Interim report Q3 2023 2023-10-27
- Year-end report 2023 2024-02-23

## INCOME STATEMENT

<i>Amounts in KSEK</i>	<i>Note</i>	<i>2022-01-01 2022-12-31</i>	<i>2021-01-01 2021-12-31</i>
Net sales		-	-
Own work capitalized	6.7	35,257	27,116
Other operating income	2	111	578
		<b>35,368</b>	<b>27,694</b>
<b><i>Operating expenses</i></b>			
Other external expenses	4	- 38,956	-29,811
Personnel expenses	3	- 5,034	-4,149
Depreciation/Write-down of tangible and intangible assets	8.7	- 17	-16
<b>Operating profit/loss</b>		<b>- 8,639</b>	<b>-6,282</b>
<b><i>Profit/loss from financial items</i></b>			
Interest income		202	68
Interest expenses		- 19	-35
<b>Profit/loss after financial items</b>		<b>- 8,456</b>	<b>-6,249</b>
<b>Profit/loss before tax</b>		<b>- 8,456</b>	<b>-6,249</b>
<b><i>Tax on profit (loss) for the year</i></b>	5	<b>-</b>	<b>-</b>
<b>Profit/loss for the year</b>		<b>- 8,456</b>	<b>-6,249</b>

## BALANCE SHEET

<i>Amounts in KSEK</i>	<i>Note</i>	<i>2022-12-31</i>	<i>2021-12-31</i>
<b>ASSETS</b>			
<b>Non-current assets</b>			
<i>Intangible assets</i>			
Capitalized expenditure for development work	6	89,866	54,771
Patent	7	68	68
		<b>89,934</b>	<b>54,839</b>
<i>Tangible assets</i>			
Equipment, tools, fixtures and fittings	8	91	61
		<b>91</b>	<b>61</b>
<b>Total non-current assets</b>		<b>90,025</b>	<b>54,900</b>
<b>Current assets</b>			
<i>Short term receivables</i>			
Account receivables		70	-
Current tax receivables		122	58
Other current receivables		1,126	387
Prepayments and accrued income		352	606
		<b>1,670</b>	<b>1,051</b>
<i>Liquid assets</i>			
		33,937	76,278
<b>Total current assets</b>		<b>35,607</b>	<b>77,329</b>
<b>TOTAL ASSETS</b>		<b>125,632</b>	<b>132,229</b>
<i>Amounts in KSEK</i>	<i>Note</i>	<i>2022-12-31</i>	<i>2021-12-31</i>
<b>EQUITY AND LIABILITIES</b>			
<i>Equity</i>			
<i>Restricted equity</i>			
Share capital		13,789	13,789
Fund for development expenditure		88,042	52,946
		<b>101,831</b>	<b>66,735</b>
<i>Non-restricted equity</i>			
Share premium fund		153,770	153,770
Retained earnings		-127,636	-86,292
Profit/loss for the year		-8,456	-6,249
		<b>17,678</b>	<b>61,229</b>
<b>Total equity</b>		<b>119,509</b>	<b>127,964</b>
<i>Non-current liabilities</i>			
Other non-current financial liabilities	9	850	850
		<b>850</b>	<b>850</b>
<i>Current liabilities</i>			
Accounts payable		3,963	2,383
Other current liabilities		146	156
Accrued expenses and prepaid income	10	1,164	875
		<b>5,273</b>	<b>3,414</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>125,632</b>	<b>132,228</b>

## CASH FLOW STATEMENT

<i>Amounts in KSEK</i>	<i>2022-01-01</i>		<i>2021-01-01</i>	
	<i>2022-12-31</i>		<i>2021-12-31</i>	
<b>The operating activities</b>				
Result after financial items	-	8,456	-	6,249
Adjustment for items not included in the cashflow				
Depreciation		17		16
<b>Cashflow from the operating activities before changes in working capital</b>	<b>-</b>	<b>8,439</b>	<b>-</b>	<b>6,233</b>
<i>Cash flow from changes in working capital</i>				
Increase(-)/Decrease (+) in current assets	-	619	-	229
Increase(+)/Decrease (-) in current liabilities		1,858	-	388
<b>Cashflow from the operating activities</b>	<b>-</b>	<b>7,200</b>	<b>-</b>	<b>6,850</b>
<b>Investment activities</b>				
Acquisitions in intangible fixed assets	-	35,095	-	26,314
Acquisitions in tangible fixed assets	-	46	-	-
<b>Cashflow from investment activities</b>	<b>-</b>	<b>35,141</b>	<b>-</b>	<b>26,314</b>
<b>Financing activities</b>				
Issue of exercised warrants		-		27,532
New share issue		-		42,000
Fund raising costs		-	-	3,241
<b>Cashflow from financing activities</b>		<b>-</b>		<b>66,291</b>
<b>This year's cashflow</b>	<b>-</b>	<b>42,341</b>		<b>33,127</b>
<b>Cash and cash equivalents at the beginning of the year</b>		<b>76,278</b>		<b>43,151</b>
<b>Cash and cash equivalents at the end of the year</b>		<b>33,937</b>		<b>76,278</b>

## NOTES 1 - 13

### 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).

The accounting principles are unchanged from the previous year.

#### *Valuation principles, etc.*

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

#### *Intangible assets*

##### *Research and development costs*

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

- It is technically possible 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 to use or sell the intangible asset.
- It is probable that the intangible asset will generate future economic benefits.
- There are necessary and adequate technical, financial and other resources to complete the development and to use or sell the intangible asset.
- The expenditure related to the intangible asset can be reliably calculated.

##### *Other intangible assets*

Other intangible assets acquired by the company are carried at cost, less accumulated amortization and impairment.

##### *Depreciation and amortization*

Depreciation is calculated on a straight-line basis 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 commercialized.

##### *Tangible fixed assets*

Property, plant and equipment are stated at cost, less accumulated depreciation and impairment losses. In addition to the purchase price, cost includes expenses directly attributable to the acquisition. Property, plant and equipment are recognized as assets in the balance sheet when, based on available information, it is probable that the future economic benefits associated with the asset 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 the performance of the asset is improved from the level at which it was originally acquired. All other incremental costs are recognized as expenses in the period in which they are 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.

<i>Intangible assets</i>	<i>% per year</i>
Capitalized development costs	5-10
<i>Tangible fixed assets</i>	<i>% per year</i>
Equipment, tools and installations	20

### ***Impairment - tangible and intangible assets***

At each balance sheet date, it is assessed whether there is any indication that an asset's value is less than its carrying amount. If such an indication exists, the recoverable amount of the asset is calculated.

The recoverable amount is the higher of fair value, less costs to sell and value in use. In calculating the value in use, the present value of the future cash flows that the asset is expected to generate in the ordinary course of business and when it is disposed of or scrapped is calculated. The discount rate used is pre-tax and reflects market assessments of the time value of money and the risks associated with the asset. A previous impairment loss is reversed only if the reasons for calculating the recoverable amount at the time of the last impairment loss have changed.

### ***Claims***

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

### ***Revenue***

The inflow of economic benefits that the entity has received or will receive for its own account is recognized as revenue. Revenue is measured at the fair value of what has been or will be received.

### ***Public grants***

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

A government grant that is contingent on future performance is recognized as revenue when the performance is completed. If the grant is received before the conditions for recognizing it as revenue are met, the grant is recognized as a liability.

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

## **Note 2 Other operating income**

<i>Amounts in KSEK</i>	<i>2022-01-01</i>	<i>2021-01-01</i>
	<i>2022-12-31</i>	<i>2021-12-31</i>
Received grants	110	473
Other income	1	104
<b>Total</b>	<b>111</b>	<b>577</b>

### Note 3 Employee and personnel costs

	2022-01-01	2021-01-01
	2022-12-31	2021-12-31
Average number of employees women	2.5	3.0
Average number of employees men	3.5	1.0
<b>Total</b>	<b>6.0</b>	<b>4.0</b>

### Note 4 Operating leases

<i>Amounts in KSEK</i>	2022-01-01	2021-01-01
	2022-12-31	2021-12-31
Facility rent	734	710
<b>Total</b>	<b>734</b>	<b>710</b>

The cost of renting premises in the coming year is estimated at around KSEK 750 per year.

### Note 5 Tax on profit for the year

<i>Amounts in KSEK</i>	2022-01-01	2021-01-01
	2022-12-31	2021-12-31
Current tax for the year	-	-
	-	-

Total unused tax losses amount to SEK 68 152.

### Note 6 Capitalized development expenditure

<i>Amounts in KSEK</i>	2022-12-31	2021-12-31
<i>Accumulated acquisition values</i>		
-Beginning of the year	57,360	30,244
-Capitalized during the year	35,095	27,116
-Capitalization financed by contributions	- 2,589	- 2,589
<b>Accounted values at the end of the year</b>	<b>89,866</b>	<b>54,771</b>

The acquisition value has been reduced by public grants from Vinnova of KSEK 533 (2014), KSEK 253 (2015), KSEK 280 (2016), KSEK 64 (2019), KSEK 657 (2020), and KSEK 802 (2021).

### Note 7 Patent

<i>Amounts in KSEK</i>	2022-12-31	2021-12-31
<i>Accumulated acquisition values</i>		
- Beginning of the year	2,617	2,617
-Capitalized during the year	-	-
-Capitalization financed by contributions	- 24	- 24
-Write-down	- 2,525	- 2,525
<b>Accounted values at the end of the year</b>	<b>68</b>	<b>68</b>

The acquisition value has been reduced by public grants from Vinnova of KSEK 24 (2020). The write-down of patents of KSEK 2 525 thousand is based on the Company's decision to no longer maintain protection for the drug candidate TOL1 in favor of the greatly improved drug candidate TOL2.



## Note 8 Equipment, tools and installations

<i>Amounts in KSEK</i>	<i>2022-12-31</i>	<i>2021-12-31</i>
<i>Accumulated acquisition values</i>		
- Beginning of the year	215	215
- New acquisitions	46	-
<i>Accumulated depreciation</i>		
-Beginning of the year	- 153	- 138
-This year's depreciation	- 17	- 16
<b>Accounted values at the end of the year</b>	<b>91</b>	<b>61</b>

## Note 9 Other liabilities to credit institutions, long-term

<i>Amounts in KSEK</i>	<i>2022-12-31</i>	<i>2021-12-31</i>
Västra Götalandsregionen	850	850
	<b>850</b>	<b>850</b>

The loan from Region Västra Götaland is a conditional loan and there is no amortization schedule. Repayment of the loan arises in connection with the exploitation of a project. The lender can also write off the loan if the results for which financing was sought have not been achieved.

## Note 10 Accrued expenses and deferred income

<i>Amounts in KSEK</i>	<i>2022-12-31</i>	<i>2021-12-31</i>
-Personnel costs	974	721
-Other interim liabilities	190	154
	<b>1,164</b>	<b>875</b>

## Note 11 Pledged assets and contingent liabilities

<i>Amounts in KSEK</i>	<i>2022-12-31</i>	<i>2021-12-31</i>
Pledged assets and collateral, company mortgage	250	250
Contingent liabilities	None	None

## Note 12 Significant events after the end of the financial year

The composition of the Nomination Committee for the 2023 AGM was announced.

A patent application was filed to protect combination therapy with the Company's tolerogens.

A technical batch of TOL2 was produced to be used in the upcoming GLP toxicology study.

A financial contribution of approximately SEK 1.7 million was granted by the Swedish innovation agency Vinnova within the call "Swelife and Medtech4Health - Collaborative projects for better health".

## Note 13 Definitions of key figures

Balance sheet total: Total assets

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

## **SIGNATURES**

Gothenburg 2023-03-31

Ann-Charlotte Rosendahl  
Chairman of the Board

Charlotte Fribert  
Executive Director

Thomas Eldered  
Board member

Maarten Kraan  
Board member

Eva Lindgren  
Board member

Jan Mattsson  
Board member

Kristian Sandberg  
Board member

Anders Waas  
Board member

Our auditor's report was submitted on 2023-04-04  
Ernst & Young AB

Linda Sallander  
Authorized auditor