



Interim report first quarter 2022

Toleranzia AB | 556877-2866



Interim report Toleranzia AB

First quarter 2022

First quarter, 1 January – 31 March

- Net sales 0 SEK (0 SEK).
- Profit/loss after financial items -2 071 922 SEK (-1 422 555 SEK).
- Results per share -0,02 SEK (-0,03 SEK).

Number within brackets: comparison to same period previous year.

Result per share: Result for the period divided with 1110 315 231 shares as per 2022-03-31.

"Company" or "Toleranzia" relates to Toleranzia AB with Swedish registration number 556877-2866.

Significant events during the first quarter 2022

- Toleranzia announced that the Company has taken steps to secure access to the purification material required to complete the scale-up of production and large-scale manufacturing of its TOL2 drug candidate. The shortage of material, caused by the production of the Covid-19 vaccine, previously led to significant uncertainty as to when the first batch of TOL2 for the clinical trial could be produced. Now that the Company has found an additional supplier and ordered, on behalf of its manufacturing partner 3P Biopharmaceuticals, all the purification material needed for the large-scale production, the prospects for starting the study in the second half of 2023 according to the communicated timetable are strengthened.

Key financial information

(SEK)	2022-01-01	2021-01-01	2021-01-01	2020-01-01
	2022-03-31	2021-03-31	2021-12-31	2020-12-31
	3 months	3 months	12 months	12 months
Net sales	-	-	-	-
Operating profit/loss	-2 071 922	-1 422 495	-6 281 747	-4 913 149
Profit/loss for the period	-2 071 922	-1 422 555	-6 249 012	-4 894 437
Total assets	131 536 527	71 463 274	132 229 590	72 575 582
Cash flow for the period	-10 474 224	-7 662 360	33 127 325	22 293 197
Cash and bank balances	65 804 152	35 488 691	76 278 376	43 151 051
Equity	125 893 301	66 500 932	127 965 221	67 923 487
Earnings per share	-0,02	-0,03	-0,06	-0,09
Equity/assets ratio (%)	95,7	93,1	96,8	93,6
Number of shares at the end of the period (no.)	110 315 231	54 346 041	110 315 231	54 346 041
Average number of shares (no.)	110 315 231	54 346 041	70 350 922	29 296 658
Number of employees	4	4	4	4

Comments from the CEO

Process equipment and purification materials secured for large-scale production of TOL2



During the first quarter of the year, we have continued to drive Toleranzia forward in an efficient and systematic way, taking important steps towards the first clinical trial of our lead drug candidate TOL2 in myasthenia gravis.

Toleranzia's current focus is on scaling up manufacturing of the TOL2 drug candidate. In March, after intensive work to evaluate options to address the shortages and delays in the supply of manufacturing materials caused by the production of Covid-19 vaccines, we were able to secure delivery of all purification materials for large-scale manufacturing. This was achieved through a supply agreement with a new supplier of biomolecule purification materials.

Once the purification material is delivered, our manufacturing partner 3P Biopharmaceuticals is fully equipped to establish the large-scale manufacturing process. Because TOL2 is protein-based, this process is much more technically complex and time-consuming than it is for conventional chemical drugs. The establishment of a well-functioning large-scale production process will therefore be a major value-creating step forward for the project.

In addition to the production work, the Company is also focusing on the next important steps in the development of TOL2. To this end, we are currently procuring a CRO to conduct the additional toxicology studies required to bring the drug candidate into clinical trials. At the same time, preparations for a scientific advisory meeting with the EMA ahead of the first clinical trial have begun, with the aim of paving the way for obtaining regulatory approvals in time to start the clinical trial as planned, in the second half of 2023.

Every five years, the Myasthenia Gravis Foundation of America holds an International Conference to bring together all those working with myasthenia gravis, and in mid-May the 14th edition of this conference will be held in Miami, USA. Our CMO Vidar Wendel-Hansen will attend the meeting and take the opportunity to present and discuss our unique tolerance technology with leading myasthenia gravis experts. In addition, our research collaborator Konstantinos Lazaridis from the Hellenic Pasteur Institute in Athens will present our preclinical data from the TOL2 project. The meeting is well timed for Toleranzia as we are currently optimising the upcoming clinical trial, together with clinical trial design experts, and selecting the best clinical research sites to streamline patient recruitment.

Toleranzia is looking forward to an exciting year with important milestones ahead, both in the preparation for our clinical trial of TOL2 in myasthenia gravis and the development of TOL3 in ANCA vasculitis. All with the overall goal of developing treatments that can dramatically improve the quality of life and outlook for patients with serious autoimmune diseases who currently lack well-functioning treatment options. I want to thank all shareholders who are helping us make this possible.

Charlotte Fribert

CEO

Gothenburg, 6 May 2022

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.se.

Company structure

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. The Company has no shareholdings.

The share

Toleranzia's shares are traded on Nasdaq First North since 15 October 2020. Previously, the shares were traded on Spotlight Stock Market. The share has ISIN code SE0007438577 and short name TOL. The number of shares in Toleranzia as of 31 March 2022 is 110,315,231. The share capital as of 31 March 2022 amounts to SEK 13,789,404. 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.

Financial development

During the first three months, the Company has mainly invested in the development of its project portfolio in myasthenia gravis and ANCA vasculitis. At the end of the first quarter, the Company had cash and cash equivalents of approximately SEK 65.8 million (SEK 35.5 million) and an equity ratio of 95.7% (93.1%).

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). For more detailed information on the accounting principles, refer to the Company's 2021 Annual Report.

Review

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

Next reports

Interim report January-June	2022-08-26
Interim report January-September	2022-10-28
Year-end report 2022	2023-02-24

The Board of Directors and the CEO hereby certify that this interim report gives a true and balanced view of the Company's operations and financial situation.

Gothenburg, 6 May 2022

Toleranzia AB

The Board of Directors and CEO

Income statement

(SEK)	2022-01-01	2021-01-01	2021-01-01
	2022-03-31	2021-03-31	2021-12-31
	3 months	3 months	3 months
Net sales	-	-	-
Own work capitalised	8 078 874	6 419 707	27 116 062
Other operating income	21 300	234 596	577 512
	8 100 174	6 654 303	27 693 574
<i>Costs</i>			
Other external expenses	-9 131 554	-6 955 943	-29 810 635
Employee benefit expenses	-1 036 546	-1 116 845	-4 148 688
Depreciation/amortisation and impairment of property, plant and equipment and intangible fixed assets	-3 996	-4 010	-15 998
Operating profit/loss	-2 071 922	-1 422 495	-6 281 747
<i>Financial items</i>			
Financial income	-	-	67 588
Finance costs	-	-60	-34 853
Profit/loss after financial items	-2 071 922	-1 422 555	-6 249 012
Profit/loss before tax	-2 071 922	-1 422 555	-6 249 012
Profit/loss for the period	-2 071 922	-1 422 555	-6 249 012

Balance sheet

(SEK)	2022-03-31	2021-03-31	2021-12-31
Assets			
Non-current assets			
<i>Intangible non-current assets</i>			
Capitalised expenditure for development and similar	62 849 467	34 632 692	54 770 593
Patent	68 136	68 136	68 136
	62 917 603	34 700 828	54 838 729
<i>Tangible non-current assets</i>			
Equipment, tools, fixtures and fittings	57 292	73 276	61 288
	57 292	73 276	61 288
Total non-current assets	62 974 895	34 774 104	54 900 017
Current assets			
<i>Receivables</i>			
Tax receivables	74 032	130 669	58 168
Other receivables	2 280 270	665 659	386 588
Prepaid expenses and accrued income	403 178	404 151	606 441
	2 757 480	1 200 479	1 051 197
Cash and bank balances	65 804 152	35 488 691	76 278 376
Total current assets	68 561 632	36 689 170	77 329 573
TOTAL ASSETS	131 536 527	71 463 274	132 229 590

Balance sheet , continued

(SEK)	2022-03-31	2021-03-31	2021-12-31
EQUITY AND LIABILITIES			
<i>Equity</i>			
<i>Restricted equity</i>			
Share capital	13 789 404	6 793 255	13 789 404
Development expenditure fund	61 025 095	32 808 320	52 946 221
	74 814 499	39 601 575	66 735 625
<i>Unrestricted equity</i>			
Share premium fund	153 770 259	94 475 662	153 770 259
Retained earnings	-100 619 537	-66 153 750	-86 291 651
Profit/loss for the period	-2 071 922	-1 422 555	-6 249 012
	51 078 800	26 899 357	61 229 596
Total equity	125 893 299	66 500 932	127 965 221
<i>Non-current liabilities</i>			
Other non-current liabilities	850 000	850 000	850 000
	850 000	850 000	850 000
<i>Current liabilities</i>			
Trade payables	3 637 539	3 018 236	2 383 440
Other current liabilities	73 321	71 921	156 324
Accrued expenses and deferred income	1 082 368	1 022 185	874 605
	4 793 228	4 112 342	3 414 369
TOTAL EQUITY AND LIABILITIES	131 536 527	71 463 274	132 229 590

Statement of changes in equity

2022-01-01 - 2022-03-31	Share capital	Development expenditure fund	Share premium fund	Retained earnings	Profit/loss for the year
Opening balance, 1 January 2022	13 789 404	52 946 221	153 770 259	-86 291 651	-6 249 012
Transfer of profit/loss from previous year				-6 249 012	6 249 012
Internal equity transfers		8 078 874		-8 078 874	
Profit/loss for the period					-2 071 922
Closing balance, 31 March 2022	13 789 404	61 025 095	153 770 259	-100 619 537	-2 071 922

2021-01-01 - 2021-03-31	Share capital	Development expenditure fund	Share premium fund	Retained earnings	Profit/loss for the year
Opening balance, 1 January 2021	6 793 255	26 632 165	94 475 662	-55 083 158	-4 894 437
Transfer of profit/loss from previous year				-4 894 437	4 894 437
Internal equity transfers		6 176 155		-6 176 155	
Profit/loss for the period					-1 422 555
Closing balance, 31 March 2021	6 793 255	32 808 320	94 475 662	-66 153 750	-1 422 555

2021-01-01 - 2021-12-31	Share capital	Development expenditure fund	Share premium fund	Retained earnings	Profit/loss for the year
Opening balance, 1 January 2021	6 793 255	26 632 165	94 475 662	-55 083 158	-4 894 437
Issue of exercised warrants	3 018 876		24 513 272		
New share issue	3 977 273		38 022 728		
Fund raising costs			-3 241 403		
Transfer of profit/loss from previous year				-4 894 437	4 894 437
Internal equity transfers		26 314 056		-26 314 056	
Profit/loss for the period					-6 249 012
Closing balance, 31 December 2021	13 789 404	52 946 221	153 770 259	-86 291 651	-6 249 012

Statement of cash flow

(SEK)	2022-01-01	2021-01-01	2021-01-01
	2022-03-31	2021-03-31	2021-12-31
	3 months	3 months	12 months
Cash flow from operating activities			
Operating profit/loss after financial items	-2 071 922	-1 422 555	-6 249 012
<i>Adjustment for non-cash items</i>			
Depreciation/amortisation and impairments	3 996	4 010	15 998
Cash flow from operating activities before changes in working capital	-2 067 926	-1 418 545	-6 233 014
<i>Cash flow from changes in working capital</i>			
Increase (-)/decrease (+) in operating receivables	-1 706 283	-377 907	-228 625
Increase (+)/decrease (-) in operating liabilities	1 378 859	310 247	-387 726
Cash flow from operating activities	-2 395 350	-1 486 205	-6 849 365
Cash flow from investing activities			
Investments in intangible non-current assets	-8 078 874	-6 176 155	-26 314 056
Investments in tangible non-current assets	-	-	-
Cash flow from investing activities	-8 078 874	-6 176 155	-26 314 056
Cash flow from financing activities			
Issue of exercised warrants	-	-	27 532 148
New share issue	-	-	42 000 001
Fund raising costs	-	-	-3 241 403
Cash flow from financing activities	0	0	66 290 746
Cash flow for the period	-10 474 224	-7 662 360	33 127 325
Cash and cash equivalents at beginning of period	76 278 376	43 151 051	43 151 051
Cash and cash equivalents at end of period	65 804 152	35 488 691	76 278 376



Company information:

Registration number: 556811-5272

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