



Interim report second quarter 2022

Toleranzia AB | 556877-2866



Interim report Toleranzia AB

Second quarter 2022

Second quarter, 1 April – 30 June

- Net sales 0 SEK (0 SEK).
- Profit/loss after financial items -2 217 822 SEK (-1 576 639 SEK).
- Results per share -0,02 SEK (-0,03 SEK).

First six months, 1 January – 30 June

- Net sales 0 SEK (0 SEK).
- Profit/loss after financial items -4 289 745 SEK (-2 999 195 SEK).
- Results per share -0,04 SEK (-0,06 SEK).

Number within brackets: comparison to same period previous year.

Result per share: Result for the period divided with 110 315 231 shares as per 2022-06-30.

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

Significant events during the second quarter 2022

- Toleranzia's groundbreaking results, demonstrating a therapeutic proof-of-concept in a preclinical disease model for the Company's most advanced drug candidate TOL2 for the autoimmune disease myasthenia gravis, were published in the scientific journal *Frontiers in Immunology*.
- A research consortium in which Toleranzia participates as an industrial partner was granted support from the Swedish Knowledge Foundation (KK-stiftelsen). The project will support Toleranzia's drug development by investigating basic mechanisms of vascular inflammation in the Company's autoimmunity models, as well as the effect of therapeutic intervention on markers of inflammation.
- Toleranzia participated in the 14th MGFA International Conference on Myasthenia And Related Disorders, organized every five years by the Myasthenia Gravis Foundation of America (MGFA).

Significant events after the reporting period

- Torbjörn Sannerstedt was appointed as new Chief Financial Officer (CFO).

Key financial information

(SEK)	2022-04-01	2021-04-01	2022-01-01	2021-01-01
	2022-06-30	2021-06-30	2022-06-30	2021-06-30
	3 months	3 months	6 months	6 months
Net sales	-	-	-	-
Operating profit/loss	-2 249 385	-1 578 487	-4 321 308	-3 000 983
Profit/loss for the period	-2 217 822	-1 576 639	-4 289 745	-2 999 195
Total assets	128 879 721	70 684 699	128 879 721	70 684 699
Cash flow for the period	-13 276 386	-7 640 911	-23 750 610	-15 303 271
Cash and bank balances	52 527 766	27 847 780	52 527 766	27 847 780
Equity	123 675 476	64 924 292	123 675 476	64 924 292
Earnings per share	-0,02	-0,03	-0,04	-0,06
Equity/assets ratio (%)	96,0	91,9	96,0	91,9
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	110 315 231	54 346 041
Number of employees	4	4	4	4

Comments from the CEO



Toleranzia's concept attracts increasing attention on the international stage

During the second quarter of the year, Toleranzia published strong positive preclinical data on its drug candidate TOL2 for myasthenia gravis in a prestigious international scientific journal. The same data were also presented at a leading international conference on myasthenia gravis, where they attracted considerable interest. At the same time, we continued our intensive work to scale up production of TOL2 in collaboration with our manufacturing partner 3P Pharmaceuticals and to prepare for the upcoming clinical trial of the drug candidate.

Strong interest in our potential disease-modifying treatment

In May, world-leading scientists gathered in Miami for the 14th edition of the Myasthenia Gravis Foundation of America's International Conference and our Chief Medical Officer, Vidar Wendel-Hansen, attended to spread the word about TOL2. During the meeting two new general symptom-relieving treatments were presented but specific treatments that can stop the progression of the disease are still lacking. As our concept has the potential to eliminate the cause of the disease, interest in TOL2 was very high. Toleranzia's preclinical results were presented by our research partner Konstantinos Lazaridis from the Hellenic Pasteur Institute in Athens, and it was clear to the audience that we are on the verge of the next big breakthrough if we can show similarly good results in future clinical trials. The results were also published in the prestigious scientific journal *Frontiers in Immunology*, further raising awareness of our treatment concept.

As myasthenia gravis is a rare disease, it is critical to find the right investigators and the most suitable clinical sites for the first clinical trial with TOL2. The growing interest in our concept puts us in a favorable position to conduct a good study and is a clear indication of the great need for a disease-modifying treatment.

Strengthened resources through research grants and new recruitment

Another external confirmation of the strength of our concept came when the Swedish Knowledge Foundation granted funding to a research consortium that will focus on anti-inflammatory drugs in areas such as vascular inflammation. Toleranzia's drug candidate TOL3 targets the autoimmune disease ANCA vasculitis and the consortium will provide us with valuable external expertise and resources to intensify our work in documenting the efficacy of our drug candidates in preclinical disease models.

At the same time, Toleranzia expanded its in-house organization during the quarter with two experienced cell biologists who are working to identify the mechanism of action behind the powerful tolerance induction provided by TOL2. After the reporting period, we also recruited a new CFO, who started on 15 August.

Continued intensive work to establish large-scale production of TOL2

Together with our manufacturing partner, we are making extensive efforts to establish large-scale production of TOL2 as quickly as possible. A shortage of certain necessary equipment and materials still remains in the wake of the covid pandemic, but, assuming key subcontractors can overcome supply issues, our goal remains to initiate the first clinical trial by the end of 2023 - a hugely important milestone in our efforts to bring a breakthrough treatment to critically ill patients while creating significant value for our shareholders.

Charlotte Friberg
CEO

Gothenburg, 26 August 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. The number of shares in Toleranzia as of 30 June 2022 is 110,315,231. The share capital as of 30 June 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 second quarter, the Company had cash and cash equivalents of SEK 52.5 million (SEK 27.8 million) and an equity ratio of 96 % (92 %).

Principles for accounting and reporting

The interim report has been prepared in accordance with the Swedish Annual Accounts Act and the Swedish Accounting Standards Board's general guidelines BFNAR 2012:1 on annual financial statements and consolidated financial statements (K3).

The cash flow statement is prepared using the indirect method. The reported cash flow includes only transactions involving receipts or payments.

In addition to cash and cash equivalents, the Company classifies as cash and cash equivalents available deposits with banks and other credit institutions and short-term liquid investments that are quoted in a marketplace and have a maturity of less than three months from the date of acquisition.

Otherwise, reference is made to the accounting policies set out in the 2021 Annual Report and applicable to the Company.

Review

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

Financial calendar

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, 26 August 2022

Toleranzia AB

The Board of Directors and CEO

Income statement

(SEK)	2022-04-01	2021-04-01	2022-01-01	2021-01-01	2021-01-01
	2022-06-30	2021-06-30	2022-06-30	2021-06-30	2021-12-31
	3 months	3 months	6 months	6 months	12 months
Net sales	-	-	-	-	-
Own work capitalised	11 577 278	7 624 892	19 656 152	14 044 598	27 116 062
Other operating income	90	224 770	1 107	459 366	577 512
	11 577 368	7 849 662	19 657 259	14 503 964	27 693 574
<i>Costs</i>					
Other external expenses	-12 423 220	-8 306 477	-21 534 492	-15 262 420	-29 810 635
Employee benefit expenses	-1 399 537	-1 117 676	-2 436 083	-2 234 521	-4 148 688
Depreciation/amortisation and impairment of property, plant and equipment and intangible fixed assets	-3 996	-3 996	-7 992	-8 006	-15 998
Operating profit/loss	-2 249 385	-1 578 487	-4 321 308	-3 000 983	-6 281 747
<i>Financial items</i>					
Financial income	40 223	28 000	40 223	28 000	67 588
Finance costs	-8 660	-26 152	-8 660	-26 212	-34 853
Profit/loss after financial items	-2 217 822	-1 576 639	-4 289 745	-2 999 195	-6 249 012
Profit/loss before tax	-2 217 822	-1 576 639	-4 289 745	-2 999 195	-6 249 012
Profit/loss for the period	-2 217 822	-1 576 639	-4 289 745	-2 999 195	-6 249 012

Balance sheet

(SEK)	2022-06-30	2021-06-30	2021-12-31
Assets			
Non-current assets			
<i>Intangible non-current assets</i>			
Capitalised expenditure for development and similar	74 426 745	41 905 596	54 770 593
Patent	68 136	68 136	68 136
	74 494 881	41 973 732	54 838 729
<i>Tangible non-current assets</i>			
Equipment, tools, fixtures and fittings	53 296	69 280	61 288
	53 296	69 280	61 288
Total non-current assets	74 548 177	42 043 012	54 900 017
Current assets			
<i>Receivables</i>			
Tax receivables	89 896	146 533	58 168
Other receivables	1 238 241	455 325	386 588
Prepaid expenses and accrued income	475 641	192 049	606 441
	1 803 778	793 907	1 051 197
Cash and bank balances	52 527 766	27 847 780	76 278 376
Total current assets	54 331 544	28 641 687	77 329 573
TOTAL ASSETS	128 879 721	70 684 699	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	72 602 373	40 081 224	52 946 221
	86 391 777	46 874 479	66 735 625
<i>Unrestricted equity</i>			
Share premium fund	153 770 259	94 475 662	153 770 259
Retained earnings	-112 196 815	-73 426 654	-86 291 649
Profit/loss for the period	-4 289 745	-2 999 195	-6 249 012
	37 283 699	18 049 813	61 229 598
Total equity	123 675 476	64 924 292	127 965 223
<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	2 721 031	3 681 055	2 383 440
Other current liabilities	155 931	137 101	156 322
Accrued expenses and deferred income	1 477 283	1 092 251	874 605
	4 354 245	4 910 407	3 414 367
TOTAL EQUITY AND LIABILITIES	128 879 721	70 684 699	132 229 590

Statement of changes in equity

2022-01-01 - 2022-06-30	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		19 656 152		-19 656 152	
Profit/loss for the period					-4 289 745
Closing balance, 30 June 2022	13 789 404	72 602 373	153 770 259	-112 196 815	-4 289 745

2021-01-01 - 2021-06-30	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		13 449 059		-13 449 159	
Profit/loss for the period					-2 999 195
Closing balance, 30 June 2021	6 793 255	40 081 224	94 475 662	-73 426 754	-2 999 195

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 share options	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)	2022-04-01	2021-04-01	2022-01-01	2021-01-01	2021-01-01
	2022-06-30	2021-06-30	2022-06-30	2021-06-30	2021-12-31
	3 months	3 months	6 months	6 months	12 months
Cash flow from operating activities					
Operating profit/loss after financial items	-2 217 822	-1 576 639	-4 289 745	-2 999 195	-6 249 012
<i>Adjustment for non-cash items</i>					
Depreciation/amortisation and impairments	3 996	3 996	7 992	8 006	15 998
Cash flow from operating activities before changes in working capital	-2 213 826	-1 572 643	-4 281 753	-2 991 189	-6 233 014
<i>Cash flow from changes in working capital</i>					
Increase (-)/decrease (+) in operating receivables	953 701	406 571	-752 583	28 665	-228 625
Increase (+)/decrease (-) in operating liabilities	-438 983	798 065	939 878	1 108 312	-387 726
Cash flow from operating activities	-1 699 108	-368 007	-4 094 458	-1 854 212	-6 849 365
Cash flow from investing activities					
Investments in intangible non-current assets	-11 577 278	-7 272 904	-19 656 152	-13 449 059	-26 314 056
Investments in tangible non-current assets	-	-	-	-	-
Cash flow from investing activities	-11 577 278	-7 272 904	-19 656 152	-13 449 059	-26 314 056
Cash flow from financing activities					
Issue of exercised share options	-	-	-	-	27 532 148
New share issue	-	-	-	-	42 000 001
Fund raising costs	-	-	-	-	-3 241 403
Cash flow from financing activities	0	0	0	0	66 290 746
Cash flow for the period	-13 276 386	-7 640 911	-23 750 610	-15 303 271	33 127 325
Cash and cash equivalents at beginning of period	65 804 152	35 488 691	76 278 376	43 151 051	43 151 051
Cash and cash equivalents at end of period	52 527 766	27 847 780	52 527 766	27 847 780	76 278 376



Company information:

Registration number: 556811-5272

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