



Interim report third quarter 2022

Toleranzia AB (publ) | 556877-2866



Interim report Toleranzia AB

Third quarter 2022

Second quarter, 1 July – 30 September

- Net sales amounted to -- KSEK (--)
- Profit after financial items amounted to SEK -2,121 thousand (-1,524)
- Cash flow from operating activities amounted to SEK -2 595 000 (-916)
- Investments in intangible assets amounted to SEK 2 350 thousand (7 113)
- Earnings per share amounted to SEK -0.02 (-0.02)

Ninth months, 1 January – 30 September

- Net sales amounted to -- KSEK (--)
- Profit after financial items amounted to KSEK -6 410 (-4 523)
- Cash flow from operating activities amounted to KSEK -6 689 (-2 770)
- Investments in intangible assets amounted to SEK 22 006 thousand (20 562)
- Earnings per share amounted to SEK -0.06 (-0.08)

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

Significant events during the third quarter 2022

- Toleranzia initiated a collaboration with Dr Amy Rosenberg, former head of the FDA's Division of Therapeutic Proteins, to obtain regulatory advice.
- Torbjörn Sannerstedt was appointed as the new Chief Financial Officer (CFO).

Significant events after the reporting period

- Toleranzia and 3P Pharmaceuticals, the company's contract manufacturing partner, started production of the first pilot batch of TOL2 where all process steps are implemented on a large scale.

Key financial data

	2022-07-01 2022-09-30 3 months	2021-07-01 2021-09-30 3 months	2022-01-01 2022-09-30 9 months	2021-01-01 2021-09-30 9 months	2021-01-01 2021-12-31 12 months
Net sales KSEK	-	-	-	-	-
Operating profit/loss KSEK	- 2 137	- 1 524	- 6 458	- 4 525	- 6 282
Profit/loss for the period KSEK	- 2 121	- 1 524	- 6 410	- 4 523	- 6 249
Total assets KSEK	125 968	136 745	125 968	136 745	132 230
Cash flow for the period KSEK	- 4 945	58 262	- 28 695	42 959	33 127
Cash and bank balances KSEK	47 583	86 110	47 583	86 110	76 278
Equity KSEK	121 555	129 691	121 555	129 691	127 965
Earnings per share SEK	- 0,02	- 0,02	- 0,06	- 0,08	- 0,06
Equity/assets ratio (%)	96,5	94,8	96,8	-	96,8
Number of shares at the end of the period (no.)	110 315 231	78 497 048	110 315 231	78 497 048	110 315 231
Average number of shares (no.)	110 315 231	62 396 377	110 315 231	57 029 486	70 350 922
Number of employees and consultants	9	5	7	6	6

Comments from the CEO

Focusing on the production of TOL2



The next major value-adding step for Toleranzia is when we complete the large-scale production of TOL2. In this work we are now, together with our partner 3P, carrying out a pilot batch where all process steps are implemented and evaluated on a large scale. Once the pilot batch and subsequent analytical work is completed, we will have a solid basis for establishing the large-scale manufacturing process for TOL2. As TOL2, like many biologics, has a complex manufacturing process, we have a patent application pending for the manufacturing method, which together with the orphan drug status already obtained, will allow us to create a very strong commercial protection for the treatment in the future.

In parallel with the important steps in large-scale manufacturing, detailed planning continues for the upcoming clinical trial of TOL2, including the selection of biomarkers to evaluate the clinical efficacy of the treatment, dialogue with study sites to be included in the trial and development of the final study design to deliver high quality data. We look forward to meeting the high international interest in TOL2 by validating our drug candidate step by step and creating the best conditions to enter into a successful partnership with an established international pharmaceutical company.

New drug successes boost interest in TOL2

Over the past quarter, we have focused on raising awareness of our drug candidate TOL2 for myasthenia gravis. In September we were present in Malmö during the Nordic Life Science Days, after the end of the quarter we participated in the BioPharm America virtual networking meeting and in early November we will participate virtually during the European life science conference Bio-Europe. Shortly thereafter we will also meet with investors and potential partners during the ChinaBio Partnering Forum.

Increased international interest in TOL2

During the many partnering meetings this autumn, it has become clear that international interest in TOL2 is growing. Although new drugs for the treatment of myasthenia gravis have reached the market in the past year and several projects have advanced into clinical phase, we are seeing an increased interest and demand for information about our drug candidate TOL2, which is the only potential disease-modifying treatment in development. The sales success of the newly introduced treatments for myasthenia gravis further contributes to this curiosity. These therapies are rapidly gaining acceptance despite the fact that they only relieve symptoms and do not address the cause of the disease. Given the very promising preclinical results we have seen for TOL2, it is understandable that our pioneering project - which has the potential to actually cure the disease - is attracting a lot of interest.

Charlotte Fribert

CEO

Gothenburg, 28 October 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.

Financial development and position

The period July – September 2022

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

Other income amounted to 59 KSEK (--) during the period and consists of currency exchange rate gains.

Operating expenses for the Company amounted to 4 546 KSEK (8 843) during the period, of which 1 211 KSEK (820) are costs for personnel.

The increased costs are in line with the Company's plan and expectations linked to the long-term strategy. The cost of personnel has increased compared to last year, as a result of the increase in the number of human resources compared to previous quarters.

Of the total cost 2 350 KSEK (7 319) relates to development of the Company product portfolio within myasthenia gravis and ANCA vasculitis and the costs incurred are capitalized on an ongoing basis as own-account work.

Operating income during for the period amounted to -2 137 KSEK (-1 524).

The period January – September 2022

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

Other income amounted to 72 KSEK (459) during the period and consists of currency exchange rate gains, together with contributions from Vinnova.

Operating expenses for the Company amounted to 28 536 KSEK (26 348) during the period, of which 3 646 KSEK (3 054) are costs for personnel.

In 2022, the company has added human resources equivalent to three positions to the organization - one protein chemist and two cell biologists.

Of the total cost 22 006 KSEK (21 364) relates to development of the Company product portfolio within myasthenia gravis and ANCA vasculitis and the costs incurred are capitalized on an ongoing basis as own-account work. Development work costs correspond to 77% (81%) of the Company's total operating expenses.

Operating income for the period amounted to -6 458 KSEK (-4 525).

Cash flow and liquidity

Cash flow from operating activities for the third quarter 2022 amounted to -2 595 KSEK (-916). For the period January - September 2022 cash flow from operating activities amounted to -6 689 KSEK (-2 770).

As of September 30, 2022, the cash balance amounted to 47 583 KSEK (86 110).

Investment

Total investments in intangible assets amounted to SEK 2,350 thousand (7,113) in the third quarter of 2022. Total investments in intangible assets amounted to SEK 22,006 thousand (20,562) for the period January - September 2022.

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

Personnel resources

Toleranzia is a development company where dedicated employees with solid experience and excellence are a prerequisite for commercial success and for achieving the company's vision. In 2022, the company recruited three new people and the company had nine full-time equivalent employees or contracted consultants as of 30 September 2022.

Financing

During the autumn of 2021, the company carried out a new share issue, raising capital and cash of SEK 69 532 thousand in total, before issue costs.

The company has a continuous focus on cash flow and has ongoing discussions with its major shareholders to ensure sustainable financing of ongoing and future development projects. The existing working capital is, in the opinion of the Board of Directors, sufficient for the current needs according to the business plan for the next nine months.

In light of the above, the report has been prepared on a going concern basis as it is the assessment of management and the Board that there are a number of options available to obtain long-term financing.

Related party transactions

The company has related transactions concerning the purchase of administrative services from the company GU Ventures AB in Gothenburg. The services purchased have been made on market terms.

Ongoing unrest in Europe

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

Share

Toleranzia's shares have been traded on Nasdaq First North since 15 October 2020. The number of shares in Toleranzia as of 30 September 2022 was 110,315,231. The share capital amounted to SEK 13,789,404 as of 30 September 2022. The Company has one class of shares, each share having a quotient value of SEK 0.125 (0.125 SEK) and carrying equal rights to participate in the Company's assets and profits.

There are no outstanding option plans at the time of issuance of this interim report.

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

Ownership per September 30, 2022

Aktieägare	Andel av kapitalet	Andel av rösterna
Flerie Invest	30,0%	30,0%
Avanza Pension	6,7%	6,7%
Nordnet Pension	5,3%	5,3%
Niklas Bergström	3,4%	3,4%
Gunvald Berger	2,7%	2,7%
Måns Flodberg	2,4%	2,4%
GU Ventures	2,4%	2,4%
Sören Christensen	2,0%	2,0%
Nordea Pension	1,6%	1,6%
Lars Molinder	1,4%	1,4%
Others	42,1%	42,1%
Total	100,0%	100,0%

Review

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

Financial calendar

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, 28 October 2022

Toleranzia AB (publ)

Ann-Charlotte Rosendahl Styrelseordförande	Charlotte Fribert Verkställande direktör	Thomas Eldered Styrelseledamot
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Maarten Kraan Styrelseledamot	Eva Lindgren Styrelseledamot	Jan Mattsson Styrelseledamot
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Kristian Sandberg Styrelseledamot	Anders Waas Styrelseledamot
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The English version of the quarterly report is an internal translation. In case of any discrepancies, the Swedish text applies.

For further information, please contact:

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Income statement

(KSEK)	2022-07-01	2021-07-01	2022-01-01	2021-01-01	2021-01-01
	2022-09-30	2021-09-30	2022-09-30	2021-09-30	2021-12-31
	3 months	3 months	9 months	9 months	12 months
Net sales	-	-	-	-	-
Own work capitalised	2 350	7 319	22 006	21 364	27 116
Other operating income	59	-	72	459	578
	2 408	7 319	22 078	21 823	27 694
Costs					
Other external expenses	- 3 331	- 8 019	- 24 878	- 23 282	- 29 811
Employee benefit expenses	- 1 210	- 820	- 3 646	- 3 054	- 4 149
Depreciation/amortisation and impairment of property, plant and equipment and intangible fixed assets	- 4	- 4	- 12	- 12	- 16
Operating profit/loss	- 2 137	- 1 524	- 6 458	- 4 525	- 6 282
Financial items					
Financial income	20	-	61	28	68
Finance costs	- 4	-	- 13	- 26	- 35
Profit/loss after financial items	- 2 121	- 1 524	- 6 410	- 4 523	- 6 249
Profit/loss before tax	- 2 121	- 1 524	- 6 410	- 4 523	- 6 249
Profit/loss for the period	- 2 121	- 1 524	- 6 410	- 4 523	- 6 249

Balance sheet

(KSEK)	2022-09-30	2021-09-30	2021-12-31
ASSETS			
Non-current assets			
Intangible non-current assets			
Capitalised expenditure for development and similar	76 777	49 018	54 772
Patent	68	68	68
	76 845	49 086	54 840
Tangible non-current assets			
Equipment, tools, fixtures and fittings	49	65	61
	49	65	61
Total non-current assets	76 894	49 151	54 901
Current assets			
Receivables			
Tax receivables	100	162	58
Other receivables	914	990	387
Prepaid expenses and accrued income	477	331	606
	1 491	1 483	1 051
Cash and bank balances	47 583	86 110	76 278
Total current assets	49 074	87 593	77 329
TOTAL ASSETS	125 968	136 744	132 230

Balance sheet , continued

(KSEK)	2022-09-30	2021-09-30	2021-12-31
EQUITY AND LIABILITIES			
<i>Equity</i>			
<i>Restricted equity</i>			
Share capital	13 790	9 812	13 789
Share issue ongoing	-	3 977	-
Development expenditure fund	74 775	47 194	52 947
	88 565	60 983	66 736
<i>Unrestricted equity</i>			
Share premium fund	153 770	153 770	153 770
Retained earnings	- 114 370	- 80 539	- 86 292
Profit/loss for the period	- 6 410	- 4 523	- 6 249
	32 990	68 708	61 229
Total equity	121 555	129 691	127 965
<i>Non-current liabilities</i>			
Other non-current liabilities	850	850	850
	850	850	850
<i>Current liabilities</i>			
Trade payables	1 908	4 991	2 383
Other current liabilities	90	74	156
Accrued expenses and deferred income	1 565	1 138	876
	3 563	6 203	3 415
TOTAL EQUITY AND LIABILITIES	125 968	136 744	132 230

Statement of changes in equity

2022-01-01 - 2022-09-30 (KSEK)	Share capital	Development expenditure fund	Share premium fond	Retained earnings	Profit/loss for the year
Opening balance, 1 January 2022	13 789	52 946	153 770	- 86 292	- 6 249
Transfer of profit/loss from previous year	-	-	-	- 6 249	6 249
Internal equity transfers	-	22 006	-	- 22 006	-
Profit/loss for the period	-	-	-	-	6 410
Closing balance, 30 September 2022	13 789	74 952	153 770	- 114 547	- 6 410

2021-01-01 - 2021-09-30 (KSEK)	Share capital	Development expenditure fund	Share premium fond	Retained earnings	Profit/loss for the year
Opening balance, 1 January 2021	6 793	26 632	94 476	- 55 083	- 4 894
Issue of exercised share options	3 019	-	24 513	-	-
New share issue	3 977	-	38 023	-	-
Fund raising costs	-	-	- 3 241	-	-
Transfer of profit/loss from previous year	-	-	-	- 4 894	4 894
Internal equity transfers	-	20 562	-	- 20 562	-
Profit/loss for the period	-	-	-	-	4 523
Closing balance, 30 September 2021	13 789	47 194	153 771	- 80 539	- 4 523

2021-01-01 - 2021-12-31 (KSEK)	Share capital	Development expenditure fund	Share premium fond	Retained earnings	Profit/loss for the year
Opening balance, 1 January 2021	6 793	26 632	94 476	- 55 083	- 4 894
Issue of exercised share options	3 019	-	24 513	-	-
New share issue	3 977	-	38 023	-	-
Fund raising costs	-	-	- 3 241	-	-
Transfer of profit/loss from previous year	-	-	-	- 4 894	4 894
Internal equity transfers	-	26 314	-	- 26 314	-
Profit/loss for the period	-	-	-	-	6 249
Closing balance, 31 December 2021	13 789	52 946	153 771	- 86 291	- 6 249

Statement of cash flow

(KSEK)	2022-07-01	2021-07-01	2022-01-01	2021-01-01	2021-01-01
	2022-09-30	2021-09-30	2022-09-30	2021-09-30	2021-12-31
	3 months	3 months	9 months	9 months	12 months
Cash flow from operating activities					
Operating profit/loss after financial items	- 2 121	- 1 524	- 6 410	- 4 523	- 6 249
<i>Adjustment for non-cash items</i>					
Depreciation/amortisation and impairments	4	4	12	12	16
Cash flow from operating activities before changes in working capital	- 2 117	- 1 520	- 6 398	- 4 511	- 6 233
<i>Cash flow from changes in working capital</i>					
Increase (-)/decrease (+) in operating receivables	313	- 689	- 440	- 661	- 229
Increase (+)/decrease (-) in operating liabilities	- 791	1 293	149	2 402	- 388
Cash flow from operating activities	- 2 595	- 916	- 6 689	- 2 770	- 6 850
Cash flow from investing activities					
Investments in intangible non-current assets	- 2 350	- 7 113	- 22 006	- 20 562	- 26 314
Investments in tangible non-current assets	-	-	-	-	-
Cash flow from investing activities	- 2 350	- 7 113	- 22 006	- 20 562	- 26 314
Cash flow from financing activities					
Issue of exercised share options	-	27 532	-	27 532	27 532
New share issue	-	42 000	-	42 000	42 000
Fund raising costs	- -	3 241	- -	3 241	- 3 241
Cash flow from financing activities	-	66 291	-	66 291	66 291
Cash flow for the period	- 4 945	58 262	- 28 695	42 959	33 127
Cash and cash equivalents at beginning of period	52 528	27 848	76 278	43 151	43 151
Cash and cash equivalents at end of period	47 583	86 110	47 583	86 110	76 278

General

Toleranzia AB (publ), Corp. Id. No 556877-2866 is a Company registered in Sweden and domiciled in Gothenburg, with address Arvid Wallgrens backe 20, 413 46 Gothenburg, Sweden.

All amounts are stated in KSEK unless stated otherwise. Amounts in brackets refer to the comparative year.

Principles for accounting and reporting

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

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

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

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

Earnings per share

	2022-07-01 2022-09-30 3 months	2021-07-01 2021-09-30 3 months	2022-01-01 2022-09-30 9 months	2021-01-01 2021-09-30 9 months	2021-01-01 2021-12-31 12 months
Earnings per share, basic SEK	-0,02	-0,02	-0,06	-0,08	-0,09
Performance measures used in the calculation of earnings per share					
Profit (loss) attributable to Company shareholders, SEK	- 2 121	- 1 524	- 6 410	- 4 523	- 6 249
Number					
Number of shares at the end of the period	110 315 231	78 497 048	110 315 231	78 497 048	110 315 231
Average number of shares	110 315 231	62 396 377	110 315 231	57 029 486	70 350 922

Related party transactions

Purchases of services

(KSEK)	2022-07-01 2022-09-30 3 months	2021-07-01 2021-09-30 3 months	2022-01-01 2022-09-30 9 months	2021-01-01 2021-09-30 9 months	2021-01-01 2021-12-31 12 months
GU Ventures AB	121	79	378	323	431
Total	121	79	378	323	431



Company information:

Registration number: 556811-5272

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