



Interim report second quarter 2023

Toleranzia AB (publ) | 556877-2866



INTERIM REPORT SECOND QUARTER 2023 TOLERANZIA AB (PUBL)

Three months, April 1 - June 30

- Net sales amounted to -- KSEK (--)
- Profit after financial items amounted to KSEK -2 503 (-2 218).
- Cash flow from operating activities amounted to SEK -1 238 thousand (-1 699).
- Investments in intangible assets amounted to SEK 19 659 thousand (11 577).
- Earnings per share amounted to SEK -0,02 (-0,02).

Six months, January 1 – June 30

- Net sales amounted to -- KSEK (--)
- Profit after financial items amounted to KSEK -4 450 (-4 290)
- Cash flow from operating activities amounted to KSEK -3 442 (-4 095)
- Investments in intangible assets amounted to KSEK 29 792 (19 655)
- Earnings per share amounted to SEK -0,04 (-0,04)

The "Company" or "Toleranzia" refers to Toleranzia AB with organization number 556877-2866.

Significant events in the second quarter of 2023

- Preparatory work for GMP manufacturing and GLP toxicology studies of the drug candidate TOL2

Significant events after the reporting period

- Decision to carry out an issue of units of approximately SEK 55 million
- Manufacturing steps of the GMP process for the drug substance TOL2 successfully completed
- Development of freeze-drying formulation of TOL2 drug candidate successfully completed

Key financial data

| | 2023-04-01 | 2022-04-01 | 2023-01-01 | 2022-01-01 | 2022-01-01 |
|---|-------------|-------------|-------------|-------------|-------------|
| | 2023-06-30 | 2022-06-30 | 2023-06-30 | 2022-06-30 | 2022-12-31 |
| | 3 months | 3 months | 6 months | 6 months | 12 months |
| Net sales KSEK | - | - | - | - | - |
| Operating profit/loss KSEK | - 2,489 | - 2,249 | - 4,478 | - 4,321 | - 8,639 |
| Profit/loss for the period KSEK | - 2,503 | - 2,218 | - 4,450 | - 4,290 | - 8,456 |
| Total assets KSEK | 121,959 | 128,880 | 121,959 | 128,880 | 125,632 |
| Cash flow for the period KSEK | - 20,897 | - 13,276 | - 33,234 | - 23,750 | - 42,341 |
| Cash and bank balances KSEK | 703 | 52,528 | 703 | 52,528 | 33,937 |
| Equity KSEK | 115,059 | 123,674 | 115,059 | 123,674 | 119,509 |
| Earnings per share SEK | - 0.02 | - 0.02 | - 0.04 | - 0.04 | - 0.08 |
| Equity/assets ratio (%) | 94.3 | 96.0 | 94.3 | 96.0 | 95.1 |
| Number of shares at the end of the period (no.) | 110,315,231 | 110,315,231 | 110,315,231 | 110,315,231 | 110,315,231 |
| Average number of shares (no.) | 110,315,231 | 110,315,231 | 110,315,231 | 110,315,231 | 110,315,231 |
| Number of employees and consultants | 11 | 9 | 14 | 10 | 8 |

COMMENTS FROM THE CEO

Intensive work to reach key milestones



Production of GMP materials for clinical studies

There has been a high level of activity and work pace behind the scenes in Toleranzia during the second quarter of the year and the summer months. Recently, we were able to announce that we have completed the production of a large-scale GMP batch together with our contract manufacturer and I am very pleased to note that the entire development process has run very smoothly and efficiently, completely according to our plans and requirements. The GMP batch will be used in our first clinical study with TOL2 in patients with myasthenia gravis.

New freeze-dried formulation

After the end of the period, we have also completed the development of a new optimized drug formulation of TOL2. The new formulation, which consists of a freeze-dried drug product with excellent properties, can be stably stored and reconstituted to a high concentration of active drug.

Tox study to start shortly

In mid-September, we start the important GLP toxicology study of TOL2 with a batch of the drug candidate manufactured with the new freeze-drying formulation. Charles River Laboratories in France, which has significant expertise and extensive experience in regulatory toxicology studies related to immunomodulatory drug candidates, is a key partner for this step in documenting TOL2's safety profile for future clinical studies.

Rights issue strengthens cash position

The capital raise in the form of a rights issue of units of approximately SEK 55 million that we are currently carrying out will strengthen the cash position to complete all preclinical activities and documentation of our drug candidate TOL2 and take it into clinical studies in patients with the nerve-muscle disease myasthenia gravis. The rights issue is covered to approximately 47 percent by subscription commitments. The preliminary subscription period is set to August 30 - September 13 and the outcome of the issue is expected to be presented on September 15.

Ever closer to the clinical development phase

We look forward with confidence to the results from the GLP toxicology study and upcoming interactions with regulatory authorities - two important milestones in the development program of TOL2 as they represent the final steps before the submission of the clinical trial application. Recent progress brings us ever closer to our goal - to offer a completely new type of treatment for this rare but serious disease that currently lacks a safe, disease-specific and effective therapy.

Charlotte Fribert

Executive Director

Gothenburg, August 25, 2023

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.com.

Company structure and shareholding

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. Nor does the company have any shareholdings in other companies.

Financial development and position

Period April - June

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

Other income amounted to KSEK 2 (--) during the quarter and consists mainly of currency exchange rate gains.

The company's operating expenses amounted to KSEK 22 150 (13 826) for the quarter, of which KSEK 1 505 (1 399) relates to personnel costs.

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 the previous year, as a result of an increase in the number of human resources compared to previous quarters.

Of the total cost, KSEK 19 659 (11 577) relates to the development of the company's project portfolio in myasthenia gravis and ANCA vasculitis, where the costs incurred are capitalized on an ongoing basis as own-account work.

The operating result during the quarter amounted to KSEK -2 489 (-2 249).

The period January – June

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

Other income amounted to 49 KSEK (1) during the period and consists mainly of currency exchange rate gains.

Operating expenses for the Company amounted to 34 319 KSEK (23978) during the period, of which 2 859 KSEK (2 436) are costs for personnel.

The costs for the Company's development work represent 86% (82%) of the total operating costs. The cost of development work for the Company's project portfolio in myasthenia gravis and ANCA vasculitis amounted to KSEK 29,792 (19,656). The costs incurred are capitalized on an ongoing basis as own-account work.

Operating profit/loss for the period amounted to -4 478 KSEK (-4 321).

Cash flow and liquidity

For the period April - June, cash flow from operating activities amounted to KSEK -1 238 (-1 699). For the period January - June cash flow from operating activities amounted to -3 442 KSEK (-4 095).

As of June 30, the Company's cash and bank balance amounted to KSEK 703 (52 528).

Investments

Total investments in intangible assets amounted to KSEK 19 659 (11 577) for the period April - June. Total investments in intangible assets amounted to KSEK 29 792 (19 655) for the period January - June.

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

Human resources

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. The Company had 14 full-time equivalent employees or contracted consultants as of June 30, 2023.

Financing

Toleranzia has decided to carry out an issue of units of approximately MSEK 55, consisting of shares and warrants with preferential rights for existing shareholders.

The Rights Issue in brief

- The Board of Directors of Toleranzia has, with authorization from the general meeting on 7 June 2023, resolved to carry out the Rights Issue of a maximum 110,315,231 units, corresponding to 110,315,231 shares and 110,315,231 warrants of series TO4.
- If fully subscribed, the Rights Issue would provide Toleranzia with approximately SEK 55 million before issue costs.
- In the event of full subscription and full exercise of all warrants of series TO4 in conjunction with offered units, the Company may be provided with an additional maximum of approximately SEK 55 million.
- The Rights Issue is covered to approximately 47 per cent by subscription commitments.
- All existing shareholders will receive one (1) unit right for each one (1) share owned on the record date, 25 August 2023. One (1) unit right gives the right to subscribe for one (1) unit. One (1) unit consists of one (1) newly issued share and one (1) warrant of series TO4. The subscription price per unit is SEK 0.50, corresponding to SEK 0.50 per share. The warrants are issued free of charge.
- The subscription period for the Rights Issue will run from 30 August 2023 until 13 September 2023.
- In addition, the board may decide on an over-allotment issue in the form of a directed new issue of a maximum 11,031,523 units, provided that the Rights Issue is fully subscribed. ("The Overallotment Issue")

Related party transactions

The company has related party transactions regarding the purchase of services from the company NorthX Biologics Matfors AB in Matfors. Purchased services 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 market. Raw materials and expertise are sourced from neither Russia nor Ukraine.

Shares

Toleranzia's shares are traded on Nasdaq First North Growth Market since October 15, 2020. The number of shares in Toleranzia amounted to 110,315,231 as of March 31, 2023. The share capital amounted to SEK

13,789,404 as of March 31, 2023. The Company has one class of shares, of which each share has a quota value of SEK 0.125 (SEK 0.125) and carries equal rights to participate in the Company's assets and earnings.

There are no ongoing option programs at the time of publication of this interim report.

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

Ownership June 30, 2023

| Shareholder | Share of capital | Share of Votes |
|--|------------------|----------------|
| FLERIE INVEST AB | 47,4% | 47,4% |
| FÖRSÄKRINGSAKTIEBOLAGET AVANZA PENSION | 2,7% | 2,7% |
| NORDNET PENSIONS FÖRSÄKRING AB | 2,5% | 2,5% |
| S & B CHRISTENSEN AB | 2,0% | 2,0% |
| NORDEA LIVFÖRSÄKRING SVERIGE AB | 1,8% | 1,8% |
| NORDIC TENDER AB | 1,4% | 1,4% |
| KONSTRUKTION O FÖRSÄLJNINGSAKTIEBOLAGET KFAB | 1,1% | 1,1% |
| KAUFMANN, JOHAN | 1,0% | 1,0% |
| BERGSTRÖM, NIKLAS TOBIAS | 0,9% | 0,9% |
| NAVCAP AB | 0,9% | 0,9% |
| OTHERS | 38,5% | 38,5% |
| Total | 100,0% | 100,0% |

Review by the auditor

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

Financial calendar

| | |
|------------------------|------------|
| Interim report Q3 2023 | 2023-10-27 |
| Year-end report 2023 | 2024-02-23 |

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

Göteborg, August 25, 2023

Toleranzia AB (publ)

| | | |
|--|--|---------------------------------------|
| Ann-Charlotte Rosendahl Chairman of the Board | Charlotte Friberg Chief Executive Officer | Thomas Eldered Member of the Board |
|--|--|---------------------------------------|

| | | |
|--------------------------------------|-------------------------------------|-------------------------------------|
| Maarten Kraan Member of the Board | Eva Lindgren Member of the Board | Jan Mattsson Member of the Board |
|--------------------------------------|-------------------------------------|-------------------------------------|

Kristian Sandberg
Member of the Board

For further information, please contact

| | | |
|---------------------------|-------------------------|---|
| Charlotte Friberg, VD | Phone: +46 763 19 98 98 | Email: charlotte.friberg@toleranzia.com |
| Torbjörn Sannerstedt, CFO | Phone: +46 708 66 22 55 | Email: torbjorn.sannerstedt@toleranzia.com |

The English version of the interim report is an internal translation. In case of discrepancies, the Swedish text applies.

INCOME STATEMENT

| (KSEK) | 2023-04-01 | 2022-04-01 | 2023-01-01 | 2022-01-01 | 2022-01-01 |
|---|----------------|----------------|----------------|----------------|----------------|
| | 2023-06-30 | 2022-06-30 | 2023-06-30 | 2022-06-30 | 2022-12-31 |
| | 3 months | 3 months | 6 months | 6 months | 12 months |
| Net sales | - | - | - | - | - |
| Own work capitalised | 19,659 | 11,577 | 29,792 | 19,656 | 35,257 |
| Other operating income | 2 | 0 | 49 | 1 | 111 |
| | 19,661 | 11,577 | 29,841 | 19,657 | 35,368 |
| <i>Costs</i> | | | | | |
| Other external expenses | - 20,639 | - 12,423 | - 31,447 | - 21,534 | - 38,956 |
| Employee benefit expenses | - 1,505 | - 1,399 | - 2,859 | - 2,436 | - 5,034 |
| Depreciation/amortisation and impairment of property, plant and equipment and intangible fixed assets | - 6 | - 4 | - 13 | - 8 | - 17 |
| Operating profit/loss | - 2,489 | - 2,249 | - 4,478 | - 4,321 | - 8,639 |
| <i>Financial items</i> | | | | | |
| Financial income | - | 40 | 47 | 40 | 202 |
| Finance costs | - 14 | - 9 | - 19 | - 9 | - 19 |
| Profit/loss after financial items | - 2,503 | - 2,218 | - 4,450 | - 4,290 | - 8,456 |
| Profit/loss before tax | - 2,503 | - 2,218 | - 4,450 | - 4,290 | - 8,456 |
| Profit/loss for the period | - 2,503 | - 2,218 | - 4,450 | - 4,290 | - 8,456 |

BALANCE SHEET

| (KSEK) | 2023-06-30 | 2022-06-30 | 2022-12-31 |
|---|-------------------|-------------------|-------------------|
| ASSETS | | | |
| Non-current assets | | | |
| <i>Intangible non-current assets</i> | | | |
| Capitalised expenditure for development and similar | 119 658 | 74 427 | 89 866 |
| Patent | 68 | 68 | 68 |
| | 119 726 | 74 495 | 89 934 |
| <i>Tangible non-current assets</i> | | | |
| Equipment, tools, fixtures and fittings | 78 | 53 | 91 |
| | 78 | 53 | 91 |
| Total non-current assets | 119 804 | 74 548 | 90 025 |
| Current assets | | | |
| <i>Receivables</i> | | | |
| Accounts receivable | - | - | 70 |
| Tax receivables | 171 | 90 | 122 |
| Other receivables | 809 | 1 238 | 1 126 |
| Prepaid expenses and accrued income | 472 | 476 | 352 |
| | 1 452 | 1 804 | 1 670 |
| Cash and bank balances | 703 | 52 528 | 33 937 |
| Total current assets | 2 155 | 54 332 | 35 607 |
| TOTAL ASSETS | 121 959 | 128 880 | 125 632 |
| (KSEK) | 2023-06-30 | 2022-06-30 | 2022-12-31 |
| EQUITY AND LIABILITIES | | | |
| <i>Equity</i> | | | |
| <i>Restricted equity</i> | | | |
| Share capital | 13 789 | 13 789 | 13 789 |
| Development expenditure fund | 117 833 | 72 602 | 88 042 |
| | 131 622 | 86 391 | 101 831 |
| <i>Unrestricted equity</i> | | | |
| Share premium fund | 153 770 | 153 770 | 153 770 |
| Retained earnings | - 165 883 | - 112 197 | - 127 636 |
| Profit/loss for the period | - 4 450 | - 4 290 | - 8 456 |
| | - 16 563 | 37 283 | 17 678 |
| Total equity | 115 059 | 123 674 | 119 509 |
| <i>Non-current liabilities</i> | | | |
| Other non-current liabilities | 850 | 850 | 850 |
| | 850 | 850 | 850 |
| <i>Current liabilities</i> | | | |
| Trade payables | 4 333 | 2 721 | 3 963 |
| Other current liabilities | 169 | 156 | 146 |
| Accrued expenses and deferred income | 1 548 | 1 477 | 1 164 |
| | 6 050 | 4 354 | 5 273 |
| TOTAL EQUITY AND LIABILITIES | 121 959 | 128 878 | 125 632 |

CHANGE IN EQUITY

| 2023-01-01 - 2023-06-30 (KSEK) | Share capital | Development expenditure fund | Share premium fond | Retained earnings | Profit/loss for the year |
|--|---------------|------------------------------------|--------------------------|----------------------|-----------------------------|
| Opening balance, 1 January 2023 | 13,789 | 88,042 | 153,770 | - 127,636 | - 8,456 |
| Transfer of profit/loss from previous year | - | - | - | - 8,456 | 8,456 |
| Internal equity transfers | - | 29,791 | - | - 29,791 | - |
| Profit/loss for the period | - | - | - | - | - 4,450 |
| Closing balance, 30 June 2023 | 13,789 | 117,833 | 153,770 | - 165,883 | - 4,450 |

| 2022-01-01 - 2022-06-30 (KSEK) | Share capital | Development expenditure fund | Share premium fond | Retained earnings | Profit/loss for the year |
|--|---------------|------------------------------------|--------------------------|----------------------|-----------------------------|
| Opening balance, 1 January 2022 | 13,789 | 52,947 | 153,770 | - 86,292 | - 6,249 |
| Transfer of profit/loss from previous year | - | - | - | - 6,249 | 6,249 |
| Internal equity transfers | - | 19,656 | - | - 19,656 | - |
| Profit/loss for the period | - | - | - | - | - 4,290 |
| Closing balance, 30 June 2022 | 13,789 | 72,603 | 153,770 | - 112,197 | - 4,290 |

| 2022-07-01 - 2022-12-31 (KSEK) | Share capital | Development expenditure fund | Share premium fond | Retained earnings | Profit/loss for the year |
|--|---------------|------------------------------------|--------------------------|----------------------|-----------------------------|
| Opening balance, 1 July 2022 | 13,789 | 72,603 | 153,770 | - 112,197 | - 4,290 |
| Internal equity transfers | - | 15,439 | - | - 15,439 | - |
| Profit/loss for the period | - | - | - | - | - 4,166 |
| Closing balance, 31 December 2022 | 13,789 | 88,042 | 153,770 | - 127,636 | - 8,456 |

CASH FLOW STATEMENT

| (KSEK) | 2023-04-01 2023-06-30 3 months | 2022-04-01 2022-06-30 3 months | 2023-01-01 2023-06-30 6 months | 2022-01-01 2022-06-30 6 months | 2022-01-01 2022-12-31 12 months |
|--|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|---------------------------------------|
| Cash flow from operating activities | | | | | |
| Operating profit/loss after financial items | - 2,503 | - 2,218 | - 4,450 | - 4,290 | - 8,456 |
| <i>Adjustment for non-cash items</i> | | | | | |
| Depreciation/amortisation and impairments | 6 | 4 | 13 | 8 | 17 |
| Cash flow from operating activities before changes in working capital | - 2,497 | - 2,214 | - 4,437 | - 4,282 | - 8,439 |
| <i>Cash flow from changes in working capital</i> | | | | | |
| Increase (-)/decrease (+) in operating receivables | - 119 | 954 | 218 | - 753 | - 619 |
| Increase (+)/decrease (-) in operating liabilities | 1,378 | - 439 | 777 | 940 | 1,858 |
| Cash flow from operating activities | - 1,238 | - 1,699 | - 3,442 | - 4,095 | - 7,200 |
| Cash flow from investing activities | | | | | |
| Investments in intangible non-current assets | - 19,659 | - 11,577 | - 29,792 | - 19,655 | - 35,095 |
| Investments in tangible non-current assets | - | - | - | - | 46 |
| Cash flow from investing activities | - 19,659 | - 11,577 | - 29,792 | - 19,655 | - 35,141 |
| Cash flow from financing activities | | | | | |
| Cash flow from financing activities | - | - | - | - | - |
| Cash flow for the period | - 20,897 | - 13,276 | - 33,234 | - 23,750 | - 42,341 |
| Cash and cash equivalents at beginning of period | 21,600 | 65,804 | 33,937 | 76,278 | 76,278 |
| Cash and cash equivalents at end of period | 703 | 52,528 | 703 | 52,528 | 33,937 |

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 2022 Annual Report and applicable to the Company.

Earnings per share

| | 2023-04-01 2023-06-30 3 months | 2022-04-01 2022-06-30 3 months | 2023-01-01 2023-06-30 6 months | 2022-01-01 2022-06-30 6 months | 2022-01-01 2022-12-31 12 months |
|---|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|---------------------------------------|
| Earnings per share, basic SEK | - 0.02 | - 0.02 | - 0.04 | - 0.04 | - 0.08 |
| Performance measures used in the calculation of earnings per share | | | | | |
| Profit (loss) attributable to Company shareholders, KSEK | - 2,503 | - 2,218 | - 4,450 | - 4,290 | - 8,456 |
| Number | | | | | |
| Number of shares at the end of the period | 110,315,231 | 110,315,231 | 110,315,231 | 110,315,231 | 110,315,231 |
| Average number of shares | 110,315,231 | 110,315,231 | 110,315,231 | 110,315,231 | 110,315,231 |

Related party transactions

Purchased services

| (KSEK) | 2023-04-01 2023-06-30 3 months | 2022-04-01 2022-06-30 3 months | 2023-01-01 2023-06-30 6 months | 2022-01-01 2022-06-30 6 months | 2022-01-01 2022-12-31 12 months |
|-----------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|---------------------------------------|
| NorthX Biologics Matfors AB | 389 | - | 859 | - | 370 |
| Total | 389 | - | 859 | - | 370 |



Company information

Organization number: 556877-2866

Legal form: Public limited company

Administrative address:

Erik Dahlbergsgatan 11 A

411 26 Göteborg

Visiting address

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413 46 Göteborg

Website

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