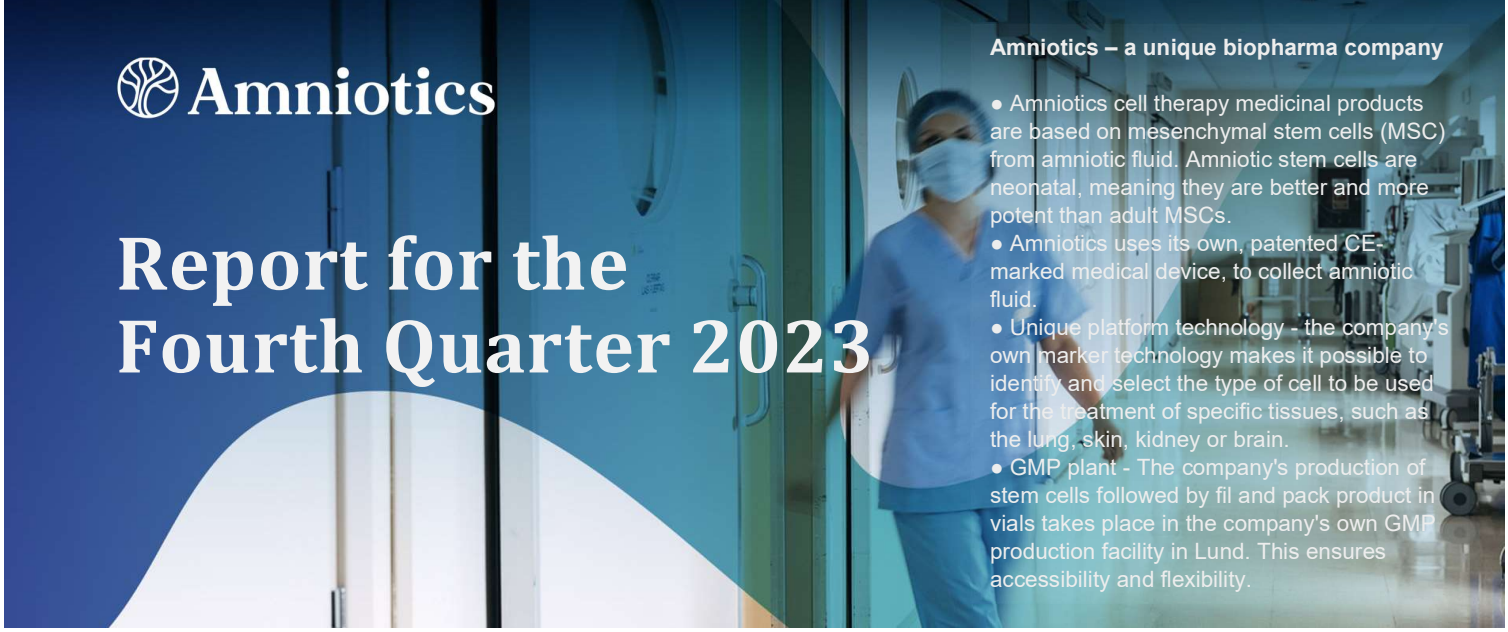
Amniotics

# Report for the Fourth Quarter 2023



**Amniotics – a unique biopharma company**

- Amniotics cell therapy medicinal products are based on mesenchymal stem cells (MSC) from amniotic fluid. Amniotic stem cells are neonatal, meaning they are better and more potent than adult MSCs.
- Amniotics uses its own, patented CE-marked medical device, to collect amniotic fluid.
- Unique platform technology - the company's own marker technology makes it possible to identify and select the type of cell to be used for the treatment of specific tissues, such as the lung, skin, kidney or brain.
- GMP plant - The company's production of stem cells followed by fil and pack product in vials takes place in the company's own GMP production facility in Lund. This ensures accessibility and flexibility.

## Orphan Designation granted in EU

### October - December in brief

- Total revenues: SEK 0 (0).
- Operating profit (EBITDA): SEK -5,0 (-9,8) million.
- Result for the period: SEK -5,8 (-10,9) million.
- Earnings per share: SEK –0,004 (-0,68).
- Cash flow for the quarter: SEK 4,6 (-14,5) million.
- Cash and cash equivalents at the end of the reporting period: SEK 8,2 (9,1) million.
- Equity/assets ratio as per the end of the reporting period: 60 (5) %.

- Amniotics carried out a rights issue that provided the company with SEK 25 million before issue costs as well as set-off and repayment of outstanding bridge loans.

- Amniotics has received renewed GMP certificate and authorization from the Swedish Medical Products Agency for the manufacture of clinical investigational drugs for advanced therapies based on mesenchymal stem cells isolated from amniotic fluid and for aseptic reconstitution of cell therapy products. The permit is valid until 2028-08-24.

- Amniotics has been granted Orphan Drug Designation for PulmoStem® for the treatment of Primary Graft Dysfunction in Lung Transplantation by the European Commission.

### Other events after the end of the reporting period

- We have been undertaking additional work to strengthen the preclinical package PulmoStem-in-PGD and are currently aiming to treat the first patient in the second half of 2024.
- The management and the board work actively to identify and evaluate various possible solutions to secure the Company's financing needs.

### January - December in brief

- Total revenues: SEK 0 (0).

- Operating profit (EBITDA): SEK -27,1 (-46,7) million.

- Result for the period: SEK -30,9 (-48) million.

- Earnings per share: SEK -0,06 (-2,99).

- Cash flow for the period: SEK -0,9 (-34,9) million.

# CEO Statement

## Orphan Designation granted in EU

A major milestone was reached for the company when the European Commission granted Orphan Designation status for PulmoStem in preventing Primary Graft Dysfunction (PGD) in lung transplantation. This gives the company several benefits during the PulmoStem product development, and a ten-year market exclusivity once the medicine is on the market. We have been working with our academic partner to plan the PulmoStem-in-PGD study in the most efficient and cost-effective way we can. We have been undertaking additional work to strengthen the preclinical package and are currently aiming to treat the first patient in the second half of 2024.

Leveraging Amniotics' manufacturing assets to provide contract services (CDMO) has remained in focus. We believe there is a poorly served niche to support academic developers and academic spin-out companies who need flexible low cost CDMO services. We have continued to promote our services at relevant congresses and via direct approach to companies and academia.

The optimization of the production of our lead candidate, PulmoStem, has continued with a strong focus on the cost of goods.

The knowledge gained from this work will also feed into our CDMO offering.

Our CNS project, CogniStem has been progressing and we are currently investigating the CNS homing mechanisms and related biochemical effects in the brain together with an academic research group at Lund University.

The NK-consortium project is on track with each consortium partner attending their separate work packages and a yearly project assembly will be held in the second quarter of 2024.

Last autumn, we carried out a rights issue. Since the net cash supplied to Amniotics did not secure the Company's working capital for the next twelve months, the plan was that the deficit would be financed by the cash that Amniotics could be supplied upon redemption of the warrants series TO3 that were issued in the rights issue where the redemption period runs during the period 26 February – 8 March 2024.

In light of the fact that the Company's share is today traded below the redemption price for TO3 of 1 öre per share, it is currently uncertain to what extent Amniotics will receive the capital injection that the TO3 warrants were planned to provide. Management and the board are now working intensively on various possible solutions to the Company's capital needs. So far we do not have a ready solution to present, but the work continues with high intensity.

Lund, February 2024
Marcus Larsson

# Amniotics in brief

## Amniotics develops and manufactures stem cell therapies in the company's own GMP certified facility

### Amniotics origin

Amniotics was born out of the discovery of a novel source of stem cells in full-term amniotic fluid. Based on a decade of research at the internationally recognized Lund University Stem Cell Center and Hospital, the company is pioneering the harvesting and propagation of tissue specific neonatal mesenchymal stem cells (MSC). Researchers and founders of the company, pediatrician Marcus Larsson, obstetrician Andreas Herbst and stem cell specialist Niels-Bjarne Woods discovered a new type of stem cells in amniotic fluid that has properties for applications in regenerative medicine.

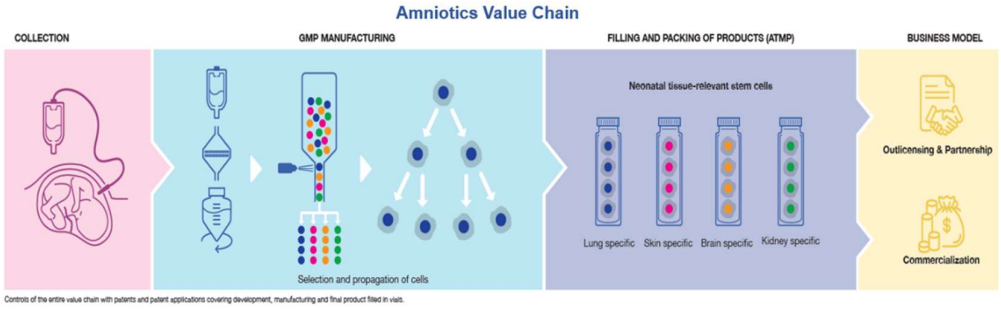
Amniotics is a biopharma company that develops cell therapy drugs based on mesenchymal stem cells (MSC) from amniotic fluid. These MSC are neonatal, which means that they are better than MSC from adult individuals in several important aspects (e.g. virus burden, growth capacity). As of now, it is Amniotics assessment that the company is the only currently active company that can produce neonatal tissue specific MSC from amniotic fluid for a number of indications. The amniotic fluid is collected during planned caesarean sections using Amniotics proprietary CE-marked medical device. Amniotics own marker technology is then used to identify and select stem cells for different tissue types:

- Lung (PulmoStem™)
- Brain (CogniStem™)
- Kidney (NephroStem™)
- Skin (CutiStem™)

### Novel treatments for unmet needs

For a number of diseases and conditions where effective treatment is currently lacking or is insufficient, stem cells can be a potential alternative. Amniotics see an opportunity to address this medical need by developing new effective treatment methods based on these neonatal tissue specific MSC.

Amniotics vision is to contribute to the successful treatment of human diseases by providing the very best stem cells for medical applications.




### Technology

Amniotics unique technology allows for selecting the type of tissue-specific neonatal stem cells to be used for specific tissue. The company has developed a process - patented in all steps - which includes collection of amniotic fluid, with a medical device developed by Amniotics, followed by sorting and propagation of stem cells and packaging of product in ampoules in its own GMP facility.

### Strategy

Amniotics strategy is to develop treatments for diseases with severe inflammatory and fibrotic components, where tissue specific stem cells are expected to have an impact on potential future life-changing treatments. The objective is to successfully conduct and complete phase I/II clinical trials. For the later stage clinical development and commercialization Amniotics intends to seek licensing partners.

Amniotics is presently producing clinical batches of lung specific MSC (PulmoStem™). With the results from Amniotics™ preclinical studies and

the characterization of the quality attributes of the cells (sterility, identity, purity, injectability Amniotics can proceed to clinical testing. All candidates are in the early development phase except PulmoStem™, which was evaluated in a clinical study during 2023 which resulted in positive Topline data with safety and tolerability being shown. Amniotics strategy also includes being an active and attractive contract manufacturer of potent MSCs to external research programs to increase the utilization rate of Amniotics GMP approved manufacturing facility.

## Several patented technologies and concepts

Large values lie in the scientific knowledge, the developed process and the technology built by Amniotics. The Company has a well-developed IP strategy that works broadly to protect this value and by protecting the Company's position in the market from competitors and competing technologies. The Company has three patent families attributable to the Company's MSC products intended for use in several treatments / indications. In addition, the Company has filed an additional 14 patent applications, of which 12 are in new patent families.

## Cell therapy market

There are only a few approved cell therapies on the market today. However, the area is expected to grow in the coming years driven by clinical successes that are accelerating investments. GlobalData estimates that the area of regulated cell therapies will reach $ 3.1 billion by 2026. Cell therapies have the potential to change future treatments due to their therapeutic potential for a variety of diseases. The US Food and Drug Administration estimates that the approval of drugs based on cell and gene therapy will increase substantially between 2021 and 2025. The first MSC-based drug to receive European approval (Alofisel from TiGenix / Takeda) was approved by the European Medicines Agency EMA in March 2018.

## Drug development with cell therapy

Amniotics focuses on the treatment of diseases where a smaller but well-defined group of patients (orphan drug designations included) has a great need for better treatment. Amniotics marker technology for identifying different populations of MSC is based on tissue-specific cell surface markers that have been identified during research and development work by the Company. Amniotics use markers and marker-specific antibodies to identify and select homogeneous and high-quality stem cells for the development of disease-specific cell therapies. The use of markers and patent-pending selection technology is one of several components that distinguish Amniotics from other stem cell companies.

## Contract development and contract manufacturing of cell therapy

Amniotics other business opportunity lies within the Company's own production service. With its own GMP production facility, Amniotics has secured production of its own products and is not dependent on outsourcing to a third party. This gives Amniotics a comparative advantage as well as control over the value chain, without the need for contracting and transferring knowhow to an external manufacturer.

Amniotics is also offering contract development and contract manufacturing of advanced therapy medicinal products (ATMPs) to the pharmaceutical industry, universities and to hospitals.

Amniotics has the capacity to work with other companies to add value through e.g.:

- Process development for ATMP at Amniotics GMP manufacturing facility in Lund
- Work with companies to help launch their products.
- Assist in solving operational challenges such as capacity constraints.

## Amniotics Pipeline

Amniotics project portfolio is based on proprietary technology and methodology. The pipeline is made up of pulmonary indications (PulmoStem™), brain indications (CogniStem™), dermatological indications (CutiStem™) and kidney-specific indications (NephroStem™).

Amniotics lung-specific product PulmoStem™ has during 2023 been evaluated in a first clinical study in humans with the primary aim of demonstrating that the product is safe and well tolerated and these goals were met. Based on favorable experimental data in a lung transplantation model, PulmoStem development will be focused on improving outcome after lung transplantation. Amniotics other cell-specific products are still at an earlier stage and will in the coming years continue to be developed towards clinical phase. iPS technology is another opportunity at an early stage with the potential to shape a new platform and a new group of indications for Amniotics. Following Phase I/II clinical trials of PulmoStem™, Amniotics intends to seek a partner for out licensing the products / technology for the development of treatment for relevant lung diseases.

**Pipeline – current prioritized areas**

| Platform | Candidate | Indication | Discovery | Preclinical | Phase I | Phase II / Partnering | Upcoming milestones |
|---|---|---|---|---|---|---|---|
| STEM CELLS (MSC) | PulmoStem™ | **ARDS (COVID-19)** | | | | | Final report H2 2023 |
| | PulmoStem™ | **Lung Transplantation** | | | | | CTA, H2 2023 |
| NK-cells (iPSC) | AMNI-NK003 | **Oncology** | | | | | GMP Optimization, H1 2024 |

**Amniotics additional platform candidates**

| Platform | Candidate | Indication | Discovery | Preclinical | Phase I | Phase II / partnering |
|---|---|---|---|---|---|---|
| STEM CELLS (MSC) | PulmoStem™ | Idiopathic pulmonary fibrosis (IPF) | | | | |
| | CogniStem™ | Neurodegenerative disease. Parkinson's, Alzheimer, ALS | | | | |
| | NephroStem™ | Acute kidney injury Transplantation | | | | |
| EVs | CutiStem™ | Epidermolysis Bullosa Burns/wound healing (Skin) | | | | |

**ARDS** - Acute Respiratory Distress Syndrome
**iPSC** - induced pluripotent stem cell
**Evs** - Extracellular vesicles
**CTA** – Clinical Trial Application to authorities to start the study

Completed
Ongoing
Planned

## Financial performance in summary

| | Quarter 4 | | January-December | |
|---|---|---|---|---|
| (KSEK) | 2023 | 2022 | 2023 | 2022 |
| Net sales | 0 | 0 | 0 | 0 |
| Operating result | -5 468 | -10 293 | -29 072 | -46 693 |
| Cash flow from operating activities | -5 195 | -13 702 | -29 090 | -46 185 |
| Cash position | 8 212 | 9 104 | 8 212 | 9 104 |
| Equity/assets ratio % | 60 | 5 | 60 | 5 |
| Earnings per share (SEK) | -0,004 | -0,68 | -0,07 | -2,99 |

# Financial overview

### Comprehensive result

Comprehensive result for the quarter was SEK -5,8 (-10,9) million, which corresponds to an improvement of SEK 5,1 million. Earnings per share, based on the number of shares at the end of the quarter, totaled SEK -0,002 (-0,68).

In the period, the comprehensive result was SEK -30,9 (-48) million, which corresponds to an improvement of SEK 17,1 million. Earnings per share, based on number of shares at end of the period, totaled SEK -0,011 (-2,99).

### Expenses

Operating expenses for the quarter totaled SEK 8,1 (10,6) million, a decrease of SEK 2,5 million. Other external costs increased by SEK 0,2 million and amounted to SEK 4,9 (4,7) million. Personnel costs amounted to SEK 2,2 (5,3) million, a decrease of SEK 3,1 million. Financial costs were TSEK 280 lower and amounted to TSEK 358 (637) thousand.

Operating expenses for the period amounted to SEK 37,4 (47,2) million, a decrease of SEK 9,8 million. Other external costs amounted to SEK 17,4 (26,6) million, a decrease of SEK 9,2 million. A large part of the reduction is due to higher costs for clinical studies in 2022 and higher consultancy costs. Personnel costs decreased by SEK 3,5 million and amounted to SEK 15 (18,5) million.

### Investments

The company's net capital expenditure during the quarter amounted to SEK 0,6 (0,7) million, including SEK 0,1 (0,4) million attributable to property, plant, and equipment, and SEK 0,5 (0,3) million relating to investments in intangible assets.

The company's net capital expenditure during the half year amounted to SEK 2,7 (3) million, including SEK 0,8 (0,9) million attributable to property, plants, and equipment, and SEK 1,9 (2,1) million relating to investments in intangible assets.

### Cash flow and financial position

Total shareholders' equity at end of the period was SEK 15,5 (1,5) million after taking the result for the quarter into account. Equity per share based on the number of outstanding shares at the end of the period was SEK 0,006 (0,092). The company's equity ratio at the end of the quarter was 60 (5) percent.

Cash and cash equivalents at the end of the period amounted to SEK 8,2 (9,1) million. Management and the Board review the capital needs and requirements to be able to continue operating the business. The company has carried out a rights issue of SEK 25 million, which is 100 percent secured. In connection with the rights issue, Amniotics has renegotiated and extended outstanding loans to Buntel AB (which has taken over previous loans from Modelio Equity AB) of approximately SEK 4.8 million. For any part of the rights issue that is subscribed for in excess of the assurance ratio (i.e. 80 percent), at least half of the volume subscribed in excess of the collateral level (up to the entire liability from the loan) shall be repaid and be received by Buntel AB after the completion of the rights issue. Half part of the loan is according to the agreement repaid. The remaining part of the loan shall be repaid on the earlier of the following occasions: one (1) banking day after the registration of the shares issued upon exercise of the warrants series TO 3 issued in the rights issue with the Swedish Companies Registration Office, and (2) on 31 March 2024.
Management and the board work intensively to identify and evaluate possible financing solutions to ensure the Company's necessary capital needs. At present, Amniotics assesses that the current liquid funds cover the Company's planned expenses until the end of March.
Cash flow for the quarter was SEK 4,6 (-14,5) million. Cash flow from financing activities totaled SEK 7,9 (0,1) million.

Cash flow for the period amounted to SEK -0,9 (-34,9) million. Cash flow from financing activities during the period amounted to SEK 28 (14,3) million.

### Organization
The number of employees at the end of the reporting period was 6, this a decrease of 11 people compared with previous year when it was 17 employees.

### Share capital
Share capital at the end of the quarter was SEK 6 505 315 and the total number of shares was 2 710 547 775 with a par value of SEK 0.0024.

# Other information

## Risks factors
A pharmaceutical development company such as Amniotics is exposed to significant operational and financial risk. Amniotics operational and external risks mainly consist of risks related to research and development, clinical trials, and dependence on key employees. Many factors can have a negative impact on the probability of commercial success. The risks to which the Company is exposed in its current phase and the risk that the necessary financing cannot be secured. During the quarter no significant changes with respect to these risks or uncertainty factors have arisen.

## Auditor's review
This report has not been reviewed by the Company's auditor.

## Liquidity and financing
The company's cash and cash equivalents at the end of the quarter amounted to SEK 8,2 (9,1) million.

The board and company management are assessing alternatives to secure the company's long-term capital requirement on an ongoing basis.

## The share
The number of shares at the end of the period amount to 2 710 547 775. All shares are of the same class and have the same voting rights. Amniotics shares are traded on Nasdaq First North Growth Market and traded under the ticker symbol AMNI and ISIN code E0015961016.

First North is Nasdaq's European emerging market intended for small, growing businesses, with a less extensive rulebook than the main market.

## Legal disclaimer
This report contains forward-looking statements that constitute subjective estimates and forecasts about the future. Assessments about the future are only valid on the date they are made and are, by their nature, like research and development work in the biotech field, associated with risk and uncertainty. Considering this, actual outcomes may differ substantially from what is described in this report.

## Future reporting dates

- Year-end Report 2023, 24 Apr 2024.
- Annual General Meeting, 22 May 2024.
- Half-year report Jan-June 2024, 20 Aug 2024.
- Second Half-year report, July-Dec 2024, 18 Febr 2025.

The financial reports will be made available on Amniotics website:

https://www.amniotics.com/investors/financial-reports/

## For further information, please contact
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## Certification by the Board of Directors and Chief Executive Officer

The Board of Directors and the Chief Executive Officer certify that this interim report provides a true and fair overview of the development of the Company's business activities, financial position and results of operations and describes significant risks and uncertainties facing the Company.

Lund, February 23th, 2024

**Amniotics AB (publ)**

| | | |
|---|---|---|
| Marcus Larsson<br>CEO | Peter Buhl Jensen<br>*Chairman* | Ingrid Atteryd Heiman<br>*Board member* |
| Christopher Bravery<br>*Board member* | Fredrik Tiberg<br>*Board member* | |

# Financial Statements

## Income statement in Summary

| | Quarter 4 | | Full-Year | |
|---|---|---|---|---|
| **SEK 000** | **2023** | **2022** | **2023** | **2022** |
| Other operating income | 2 276 | 351 | 6 495 | 553 |
| **Operating income** | **2 276** | **351** | **6 495** | **553** |
| **Operating expenses** | | | | |
| Other external costs | -4 873 | -4 711 | -17 052 | -26 622 |
| Personnel costs | -2 168 | -5 301 | -15 031 | -18 507 |
| Other operating costs | -232 | -164 | -1 184 | -324 |
| **Operating result before depreciation and amortization (EBITDA)** | **-4 996** | **-9 825** | **-26 772** | **-44 900** |
| Depreciation of tangible and intangible assets | -471 | -468 | -2 301 | -1 793 |
| **Operating result (EBIT)** | **-5 468** | **-10 293** | **-29 072** | **-46 693** |
| Net financial items | -358 | -637 | -1 797 | -1 353 |
| **Result after financial items** | **-5 826** | **-10 930** | **-30 870** | **-48 046** |
| Taxes | 0 | 0 | 0 | 0 |
| **Result for the period** | **-5 826** | **-10 930** | **-30 870** | **-48 046** |

| | Quarter 4 | | Full-Year | |
|---|---|---|---|---|
| | **2023** | **2022** | **2023** | **2022** |
| **Earnings per share** (SEK)* | -0,002 | -0,68 | -0,011 | -2,99 |
| **Earnings per weighted average number of share (SEK)**** | -0,004 | -0,68 | -0,07 | -2,99 |
| **Earnings per shares before dilution of shares***** | -0,028 | -0,68 | -1,92 | -2,99 |
| **Earnings per shares before dilution of shares****** | -0,36 | -0,68 | -1,92 | -2,99 |
| **Number of shares** | | | | |
| Weighted average for the period after dilution of shares | 1 459 525 725 | 16 066 033 | 456 355 099 | 16 066 033 |
| Weighted average for the period before dilution of shares | 16 066 033 | 16 066 033 | 16 066 033 | 16 066 033 |
| Number of shares at start of period | 208 503 675 | 16 066 033 | 16 066 033 | 16 066 033 |
| Number of shares at end of period | 2 710 547 775 | 16 066 033 | 2 710 547 775 | 16 066 033 |

** Based on number of shares at end of period*

***Based on weighted average number of shares for the period*

****Based on number of shares at start of period*

*****Based on number of shares per 23-01-01*

# Balance sheet in Summary

| SEK 000 | December 31st 2023 | 2022 |
|---|---|---|
| **Assets** | | |
| **Fixed assets** | | |
| Intangible assets | 8 090 | 6 552 |
| Equipment and installations | 5 625 | 6 798 |
| **Total fixed assets** | **13 716** | **13 350** |
| **Current assets** | | |
| Inventory | 534 | 0 |
| Other receivables | 3 625 | 6 464 |
| Cash and bank balances | 8 212 | 9 104 |
| **Total current assets** | **12 370** | **15 568** |
| **Total assets** | **26 086** | **28 918** |
| **Shareholders' Equity and Liabilities** | | |
| **Shareholders' equity** | | |
| *Restricted equity* | | |
| Share capital | 6 505 | 869 |
| Reserve for development expenses | 167 | 167 |
| *Non- restricted equity* | | |
| Share premium reserve | 100 082 | 60 793 |
| Accumulated loss including profit/loss for the period | -91 216 | -60 346 |
| **Total shareholders' equity** | **15 539** | **1 484** |
| **Liabilities** | | |
| Current liabilities | 10 547 | 27 434 |
| **Total liabilities** | **10 547** | **27 434** |
| **Total shareholders' equity and liabilities** | 26 086 | 28 918 |

## Financial key ratios

| | | |
|---|---|---|
| Shareholders' equity per share, SEK | 0,006 | 0,092 |
| Equity/assets ratio % | 60 | 5 |

* Based on the number of shares at the end of the period.

# Changes in equity

| | Full Year | |
|---|---|---|
| SEK 000 | 2023 | 2022 |
| Opening balance | 1 484 | 49 350 |
| Issue of shares | 44 925 | 0 |
| Loss for the period | -30 870 | -48 046 |
| **Equity at end of period** | **15 539** | **1 484** |

# Cash Flow statement

| | Quarter 4 | | Full Year | |
|---|---|---|---|---|
| SEK 000 | 2023 | 2022 | 2023 | 2022 |
| Operating result | -5 467 | -10 293 | -29 072 | -46 693 |
| Adjustment for items not affecting cash flow | 2 239 | 469 | 3 698 | 1 793 |
| Interest received | 97 | 36 | 99 | 36 |
| Interest paid | -56 | -675 | - 1497 | -675 |
| Paid income tax | -12 | -154 | 0 | -154 |
| **Cash flow from operating activities before change in working capital** | **-1 997** | **-10 617** | **-26 772** | **-46 355** |
| Change in working capital | 2 744 | -3 085 | - 2 319 | 170 |
| **Cash flow from operating activities** | **-5 195** | **-13 702** | **-29 090** | **-46 185** |
| Investing activities | -994 | -672 | -2 666 | -3 027 |
| **Cash flow after investing activities** | **-6 189** | **-14 374** | **-31 756** | **-49 212** |
| Financing activities | -3 072 | -134 | -3 924 | 14 335 |
| Rights issue | 13 881 | 0 | 34 789 | 0 |
| **Change in cash and cash equivalents** | **4 619** | **-14 508** | **-892** | **-34 876** |
| **Cash and cash equivalents at the beginning of the period** | 3 593 | 23 612 | 9 104 | 43 981 |
| **Cash and cash equivalents at the end of the period** | **8 212** | **9 104** | **8 212** | **9 104** |

# Glossary

**ATMP**: Advanced Therapy Medicinal Products (ATMPs) are a new type of medicine that are based on cells, tissues, and genes. ATMPs are a type of biological medicine, and they are given for the purpose of treating or preventing diseases in humans. They can restore, correct, or modify physiological functions through their pharmacological, immunological, or metabolic actions.

**GMP**: Good manufacturing practice is a system or structure for ensuring that products are consistently produced and controlled according to quality standards. Thereby minimizing the risks involved in pharmaceutical production.

**MSC**: Mesenchymal stem cells are multipotent stem cells that are present in multiple tissues. They have a range of biological activities which have the potential to treat a range of human diseases.

**Stem cells:** Stem cells are a collective name for different types of cells with the ability for self-renewal as well as development and maturation into more specialized cells.

**PDG**: Primary graft dysfunction is a type of severe lung injury that occurs within the first 72 hours of lung transplantation and is the most common cause of early mortality.

**ARDS**: Acute respiratory distress syndrome. Several conditions can trigger inflammation in the lungs that makes it difficult for the body to oxygenate itself. Shortness of breath is a serious condition caused by inflammation. The incidence has increased markedly in connection with the covid-19 pandemic.

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