Amniotics

Report for the Third Quarter 2022

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.

Amniotics entered clinical phase

July - September in brief

- Total revenues: SEK 0 (0).
- Operating profit (EBITDA): SEK -15.3 (-9.8) million.
- Result for the period: SEK -16.4 (-10.2) million.
- Earnings per share: SEK -1.07 (-0.64).
- Cash flow for the quarter: SEK -5.5 (45.3) million.
- Cash and cash equivalents at the end of the reporting period: SEK 23.6 (54.2) million.
- Equity/assets ratio as per the end of the reporting period: 31 (92) %.
- Amniotics was granted patent in the U.S for PulmoStem™ that will provide Amniotics exclusive commercial rights until 2040 for PulmoStem™ for the use of the amniotic derived stem cell in the treatment of Acute Respiratory Distress Syndrome (ARDS).
- Amniotics board member Anders Månsson resigned from the board at his own request.
- Marcus Larsson, MD, Ph.D., was appointed as new Chief Executive Officer (CEO) of Amniotics

January - September in brief

- Total revenues: SEK 0 (0).
- Operating profit (EBITDA): SEK -36 (-39.1) million.
- Result for the period: SEK -38.1 (-40.4) million.
- Earnings per share: SEK -2.37 (-2.55).
- Cash flow for the quarter: SEK -20.4 (53.6) million.
- Amniotics AB has taken out a short-term loan of SEK 15 million to finance continued operations in accordance with existing business plan until the end of 2022.
- Amniotics, together with Skåne University Hospital, received a grant of SEK 4,8 million from Sweden's Innovation Agency, Vinnova.

Other events after the end of the reporting period

- The first patient was treated with PulmoStem™ in the company's Phase Ib clinical study evaluating the product in hospitalized patients with severe respiratory infections.
- Amendment to Phase ib study of PulmoStem approved in UK and Sweden to expand indication to severe lower respiratory tract infections caused by other viruses than SARS-CoV-2 (COVID-19).
- Natural Killer (NK) cell project patent granted in U.S for AMNI-NK003. This patent covers methods and compositions for generating hematopoietic cells and aims to produce NK cells with strong antitumor activity.

CEO Statement

Amniotics is now a biopharma company with patients in clinical trials

Our progress with PulmoStem™ has reached a major milestone as the first patient was treated in our Phase Ib study on October 11, 2022. Having progressed the first of our product pipeline into the clinic, we have now completed the transition to a clinical stage company. I am very happy and proud of the team effort at Amniotics that made this possible. The Phase Ib trial is designed with adaptive dose escalation and has the primary objective of evaluating the safety and tolerability of PulmoStem in patients with severe lower respiratory tract infections. Secondary and explorative endpoints in the study include clinical parameters, indicators of pneumonia, regeneration and general biochemical indications. At the end of the quarter, we received approval from the authorities in Sweden and UK to broaden the patient population in the study to also include patients with severe lower respiratory tract infections caused by viruses other than COVID-19 such as influenza A, metapneumovirus and RS virus. In addition to the fact that it will now be easier and faster to recruit patients, the changes in the study protocol open up further development of PulmoStem within a wider indication area. We will use the results from the study, which are expected to be presented in the second half of 2023, to plan the continued clinical development of PulmoStem.

PulmoStem has provided very promising preclinical data in primary graft dysfunction (PGD), a serious complication of lung transplantation. Another potential indication for PulmoStem is idiopathic pulmonary fibrosis (IPF) where we also have promising data in preclinical animal models. In lung diseases such as IPF or PGD, the medical need for effective treatments is very high and the current treatment options are very limited. In my opinion, we have only seen the beginning of the potential for PulmoStem as a treatment for serious lung diseases.

Amniotics has recently decided to enter the field of cell therapy in oncology, more specifically the off-shelf use of NK (Natural Killer) or killer cells. NK cell therapies have been shown in several clinical studies to be effective against both hematological and solid tumours. Our Anti-cancer platform AMNI-NK003 aims to produce NK cells with high anti-tumour activity and is based on discoveries by one of our founders. The concept is based on new mechanisms to guide iPSC stem cells to become NK cells in large volumes and with high potency. NK cells are part of the immune system, and these cells scan the body to detect and eliminate cancer cells. By making large numbers of NK cells and having them ready for immediate use, they have the potential to become a widely available cell therapy for cancer treatment. We are also evaluating the possibilities of enhancing the antitumor response by adding cancer-specific receptors to the cells. The market potential for an approved oncology cell therapy is enormous and although we are still in the early stages, I

am excited about the opportunities that the program can create for Amniotics going forward.

Our in-house GMP facility, where we produce our cells, is continuously upgraded. This is important to us as it will increase our manufacturing capacity. Another benefit is that such developments will strengthen our contract manufacturing capabilities and enable us to use spare capacity to generate revenue.

During the quarter, we worked on strengthening our patent protection. In August, we were granted our first US patent, which gives us exclusive commercial rights in the US until at least 2040 in the treatment of Acute Respiratory Distress Syndrome (ARDS). In October we received a patent approval in the US for our platform AMNI-NK003. Strong patent protection is a necessity for future commercial success.

The work to strengthen our financial situation continues and we are currently evaluating various strategic alternatives to continue enabling our intensive research and development work, now as a clinical company. Due to the current market conditions Amniotics has initiated a focused strategy to reduce cost, including reducing personnel, to prolong the runway and enabling progress on selected projects.

As the new CEO since August 30, 2022, I have had the pleasure and privilege of working with the talented people who make up Amniotics. A small team that has taken a laboratory discovery and refined it into a new product that is now being evaluated in humans for the first time. Amniotics has demonstrated its ability for this transformative process, and we will use all this experience to explore other cell therapies and continue to develop PulmoStem towards the market.

Lund, November 2022
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. The Company develops two kinds on cell therapies: one with so-called mesenchymal stem cells ("**MSC**"), with the special property that the cells are derived from different tissues of the new-born baby through amniotic fluid; lung/kidney/nervous system/skin. The other kind is so-called Natural Killer Cells ("**NK cells**") which are generated at so-called induced Pluripotent Stem Cells (iPSC) where the produced cells shall be used for cancer treatment. 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;

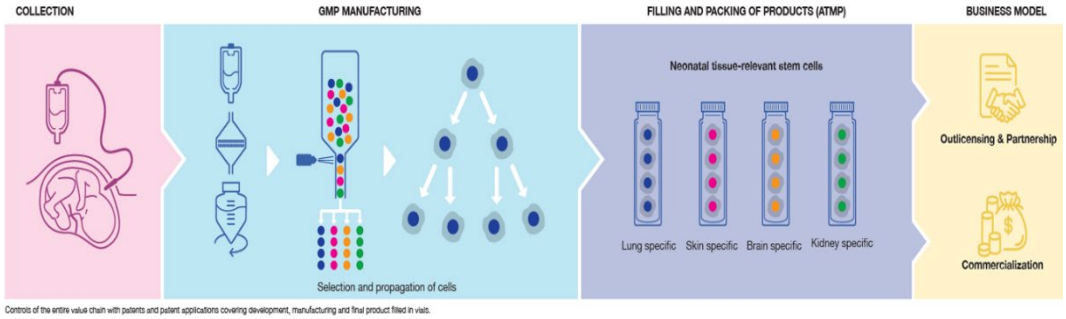
- Lung (PulmoStem™)
- Brain (CogniStem™)
- Kidney (NephroStem™)
- Skin (CutiStem™)

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 sees 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. Amniotics is devoted to developing innovative life-changing and regenerative treatments for patients.

Amniotics Value Chain



Technology

Amniotics technology allows for selecting the type of cell 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 is ready to be evaluated in a clinical study with a planned start during 2022.

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 the research and development work by the Company. Amniotics uses the 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 the 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 an comparative advantage as well as a control over the value chain.

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

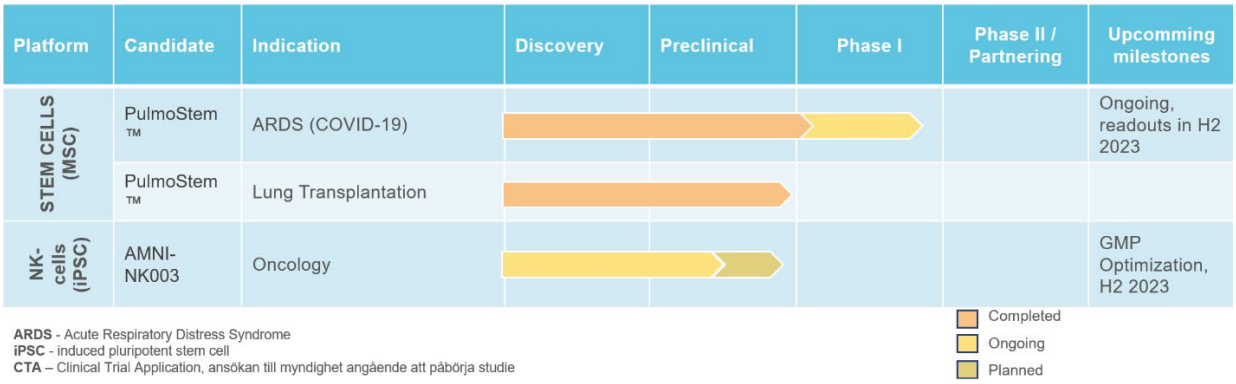
Amniotics has the capacity to work with other companies to add value through e.g.:

- 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

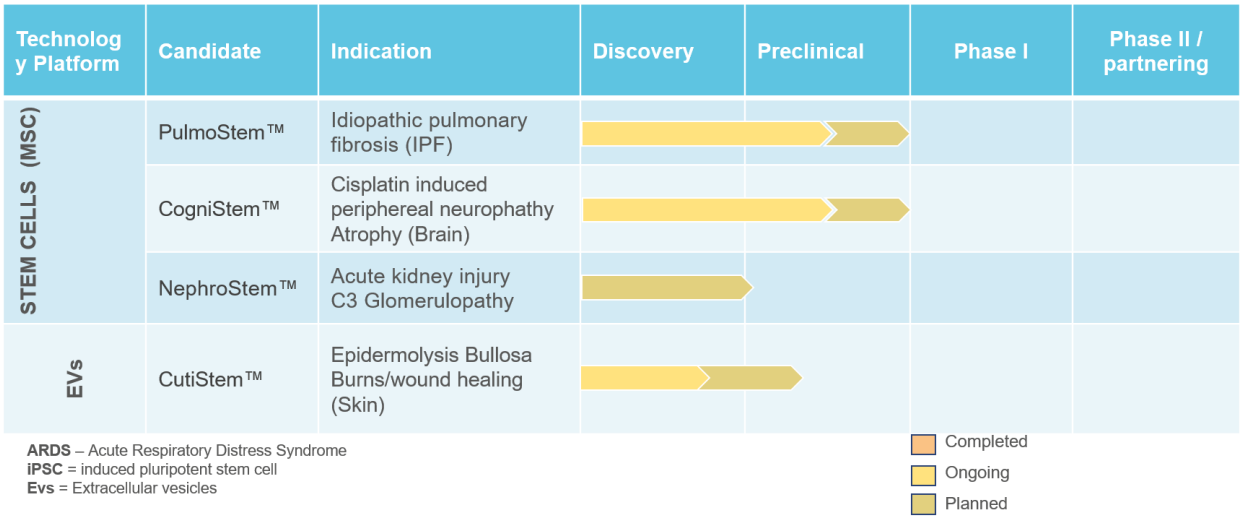
Amniotics project portfolio is based on the proprietary technology and methodology. The pipeline is made up of pulmonary indications (PulmoStem™), brain indications (CogniStem™), dermatological indications (CutiStem™) and kidney-specific indications (NephroStem™). Amniotics lung-specific product PulmoStem™ is now used in a clinical study in humans with the primary aim of demonstrating that the product is safe and well tolerated. The study can also provide an indication of the effectiveness in patient populations with relevant lung diseases. 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 – Focus areas



ARDS - Acute Respiratory Distress Syndrome
iPSC - induced pluripotent stem cell
CTA – Clinical Trial Application, ansökan till myndighet angående att påbörja studie

Amniotics other platform candidates



ARDS – Acute Respiratory Distress Syndrome
iPSC = induced pluripotent stem cell
Evs = Extracellular vesicles

Financial performance in summary

	Quarter 3		Jan - Sep		Full year
(SEK 000)	2022	2021	2022	2021	Year
Net sales	0	0	0	0	0
Operating result	-15,778	-10,211	-37,395	-40,376	-53,615
Cash flow from operating activities	-9,979	43,661	-34,192	-6,044	-15,634
Cash position	23,612	54,158	23,612	54,158	43,981
Equity/assets ratio %	31	92	31	92	85
Earnings per share (SEK)	-1.02	-0.64	-2.37	-2.55	-3.34

Financial overview

Comprehensive result
Comprehensive result for the quarter was SEK -16.4 (-10.2) million, which corresponds to a decrease of SEK 6.2 million. Earnings per share, based on number of shares at end of the quarter, totaled SEK -1.02 (-0.64).

In the period, the comprehensive result was SEK -38.1 (-40.4) million, which corresponds to an improvement of SEK -2.3 million. Earnings per share, based on number of shares at end of the period, totaled SEK -2.37 (-2.55).

Expenses
Operating expenses for the quarter totaled SEK 16.3 (9.8) million, an increase of SEK 6.3 million. Other external costs increased by SEK 4.4 million and amounted to SEK 10.6 (6.2) million. The increase is mainly due to cost for the ongoing clinical trial with PulmoStem. Personnel costs amounted to SEK 4.8 (3.6) million, an increase of SEK 1.2 million as a result of hiring of new staff during the quarter. Financial costs increased by SEK 0.6 thousand, due to taking out a short-term loan, and amounted to SEK 637 (0) thousand.

Operating expenses for the period amounted to SEK 38.8 (40.4) million, a decrease of SEK 2.1 million. Other external costs amounted to SEK 22.9 (27.3) million, a decrease of SEK 4.4 million. A large part of the reduction is due to the costs the IPO and listing on Nasdaq in 2021 of SEK 6 million, and higher consulting fees for the ongoing clinical trial. Personnel costs increased by SEK 1.6 million because of hiring of six additional employees compared to the previous year and amounted to SEK 13.2 (11.7) million.

Investments
The company's net capital expenditure during the quarter amounted to SEK 0.3 (0.04) million, including SEK 70 (300) thousand attributable to property, plant, and equipment, and SEK 274 (0) thousand relating to investments in intangible assets.

Net capital expenditure during the period amounted to SEK 1.4 (0.7) million, including SEK 0.5 (0.3) million attributable to property, plant, and equipment, mainly lab equipment, and SEK 0.9 (0.4) million relating to investments in intangible assets.

Cash flow and financial position
Total shareholders' equity at end of the period was SEK 11.4 (62.8) million after taking the result for the quarter into account. Equity per share (basic and diluted) based on the number of outstanding shares at the end of period was SEK 0.711 (3.907). The company's equity ratio at the end of the quarter was 31 (92) percent.

Cash and cash equivalents at the end of the period amounted to SEK 23.6 (54.2) million. Management and the Board review the capital needs and requirements to be able to continue operating the business. In April, Amniotics raised short term loan totaling SEK 15 million to finance the continued development and start of clinical studies and the existing operations in accordance with the company's business plan.

Cash flow for the quarter was SEK -5.5 (-45.3) million. Cash flow from financing activities totaled SEK 4.8 (60.4) million.

Cash flow for the period amounted to SEK -20.4 (53.6) million. Cash flow from financing activities during the period amounted to SEK 14.5 (60.4) million.

Organization
The number of employees at the end of the reporting period was 21, this an increase of 6 people compared with previous year when it was 15 employees. During the quarter one people have been employed in research and development.

Share capital
Share capital at the end of the quarter was SEK 869,014 and the total number of shares was 16,066,033 with a par value of SEK 0.05409.

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 23.6 (54.2) million. In April, Amniotics agreed to raise a loan of a total of SEK 15 million. The proceeds from the loans are intended to be used to finance the Company's continued development and the operations in accordance with the existing business plan until the end of 2022.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 16,033,330. All shares are of the same class and have the same voting right. 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, similar to research and development work in the biotech field, associated with risk and uncertainty. In light of this, actual outcomes may differ substantially from what is described in this report.

Future reporting dates

Year-end Report, January 1 – December 31 2022: February 24, 2023

Financial reports will be made available on Amniotics website:

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

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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, November 10th, 2022

Amniotics AB (publ)

Marcus Larsson
CEO & board member

Ingrid Atteryd Heiman
Board member

Christopher Bravery
Board member

Peter Buhl Jensen
Chairman

Fredrik Tiberg
Board member

Financial Statements

Income statement in Summary

	Quarter 3		Jan - Sep		Full-Year
SEK 000	**2022**	**2021**	**2022**	**2021**	**2021**
Other operating income	116	0	202	28	50
Operating income	116	0		28	50
		0			
Operating expenses					
Other external costs	-10,593	-6,190	-22,906	-27,321	-35,294
Personnel costs	-4,802	-3,565	-13,206	-11,653	-16,056
Other operating costs	-52	-23	-160	-142	-162
Operating result before depreciation and amortization (EBITDA)	-15,331	-9,778	-36,070	-39,088	-51,615
Depreciation of tangible and intangible assets	-447	-433	-1,325	-1,288	-2,153
Operating result (EBIT)	-15,778	-10,211	-37,395	-40,376	-53,615
Net financial items	-637	0	-714	-4	-4
Result after financial items	-16,415	-10,211	-38,109	-40,380	-53,619
Taxes	0	0	0	0	0
Result for the period	**-16,415**	-10,211	**-38,109**	-40,380	-53,619

	Quarter 3		Jan - Sep		Full-Year
	2022	**2021**	**2022**	**2021**	**2021**
Earnings per share (SEK)*	-1.02	-0.64	-2.37	-2.55	-3.34
Number of shares**					
Weighted average for the period	16,066,033	16,014,982	16,066,033	13,779,751	14,349,755
Number of shares at start of period	16,066,033	15,861,830	16,066,033	11,166,500	11,166,500
Number of shares at end of period	16,066,033	16,066,033	16,066,033	16,066,033	16,066,033

** Based on number of shares at end of period*
*** In Q2 2021 the company's shares were split in the ratio 500: 1.*

Balance sheet in Summary

SEK 000	Sep 2022	Sep 2021	Dec. 31 2021
Assets			
Subscribed but not paid share capital	0	0	0
Fixed assets			
Intangible assets	5,279	4,181	4,392
Equipment and installations	6,873	8,345	7,724
Total fixed assets	**12,152**	12,526	12,116
Current assets			
Other receivables	1,041	1,237	1,991
Cash and bank balances	23,612	54,158	43,981
Total current assets	**24,653**	55,395	45,972
Total assets	**36,805**	**67,921**	**58,088**
Shareholders' Equity and Liabilities			
Shareholders' equity			
Restricted equity			
Share capital	869	869	869
Reserve for development expenses	167	167	167
Non- restricted equity			
Share premium reserve	0	60,793	60,793
Accumulated loss including profit/loss for the period	10,385	939	-12,299
Total shareholders' equity	**11,421**	62,768	49,530
Liabilities			
Liabilities to credit institutions, long-term	0	600	0
Current liabilities	25,384	4,553	8,558
Total liabilities	**25,384**	5,153	8,558
Total shareholders' equity and liabilities	**36,805**	**67,921**	**58,088**

Financial key ratios

Shareholders' equity per share, SEK	0.711	3.907	3.083
Equity/assets ratio %	31	92	85

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

Changes in equity

SEK 000	Sep 2022	Sep 2021	Full Year 2021
Opening balance	49,530	42,186	42,186
Issue of shares	0	60,962	60,963
Loss for the period	-38,109	-40,380	-53,619
Equity at end of period	**11,421**	**62,768**	**49,530**

Cash Flow statement

SEK 000	Quarter 3 2022	Quarter 3 2021	Jan - Sep 2022	Jan - Sep 2021	Full Year 2021
Operating result	-16,415	-10,210	-38,109	-40,376	-53,616
Amortization and depreciation	447	433	1,324	1,288	2,153
Other, including non-cash items	-608	-22	-662	-89	-79
Cash flow from operating activities before change in working capital	**-16,576**	**-9,799**	**-37,447**	**-39,177**	**-51,542**
Change in working capital	6,597	53,460	-3,255	33,133	35,908
Cash flow from operating activities	**-9,979**	**43,661**	**-34,192**	**-6,044**	**-15,634**
Investing activities	-345	-42	-1,360	-689	-1,144
Cash flow after investing activities	**-10,324**	**43,616**	**-35,552**	**-6,733**	**-16,778**
Financing activities	4,801	-200	14,469	-582	-714
Rights issue		1,842		60,963	60,963
Change in cash and cash equivalents	**-5,523**	**45,261**	**-20,369**	**53,648**	**43,471**
Cash and cash equivalents at the beginning of the period	29,135	8,897	43,981	510	510
Cash and cash equivalents at the end of the period	**23,612**	**54,158**	**23,612**	**54,158**	**43,981**

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 an 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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