

Approval for clinical study with PulmoStem [™] in patients with moderate to severe covid-19

January - March in brief

- Total revenues: SEK 0 (0).
- Operating profit (EBITDA): SEK -10.6 (-12.1) million.
- Result for the period: SEK -11 (-12.5) million.
- Earnings per share: SEK -0.69 (-1.35).
- Cash flow for the quarter: SEK -11.2 (22) million.
- Cash and cash equivalents at the end of the reporting period: SEK 32.8 (22.5) million.
- Equity/assets ratio as per the end of the reporting period: 82 (71) %.
- Amniotics received a grant of SEK 4,8 million from Sweden's Innovation Agency, Vinnova, together
 with Professor Sandra Lindstedt at Skåne University Hospital. The grant will be used to demonstrate
 proof of concept of using Amniotics stem cell therapy to repair damaged discarded donor lungs for
 transplantation and for reducing the incidence of unwanted side-effects after lung transplantations.

Significant events after the end of the reporting period

 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 existing business plan.

Other events after the end of the reporting period

 In April Amniotics received approval by regulatory authorities in UK and Sweden for its first clinical trial with PulmoStem™. The study is a first-in-human Phase I/II study in hospitalized COVID-19 patients aiming to investigate the safety and tolerability of different doses of PulmoStem™

CEO Statement

The COVID-19 pandemic has taken hold again, especially in Asia. Even in the Western world, we see that it is still reaping victims. Given the developments we are currently seeing, with new variants and high infection levels, it is important to consider alternative treatments, such as stem cell therapies, which do not focus on the viral aspect of the disease. Amniotics' stem cell therapy product PulmoStem™ is not limited solely to virally induced inflammation in lung tissue. PulmoStem is expected to stop the inflammatory process and facilitate regeneration of damaged lung tissue, regardless of cause. It therefore has the potential to be useful in a variety of different respiratory indications.

Amniotics' planned Phase I/II study in hospitalized COVID-19 patients is a first-in-human clinical trial to investigate the safety and tolerability of intravenous (IV) dosing at different doses of PulmoStem in patients with moderate to severe COVID-19. We received approval for the study from the regulatory authorities in the UK and Sweden in early April. The approval in Sweden is conditional and requires an update to the application prior to initiating the study. In all, 9-18 hospitalized patients will be included in the study, which will also have secondary and exploratory endpoints related to lung regeneration effects, inflammatory response biomarkers and other clinical efficacy outcomes. We are now working diligently on the preparations for the study and expect to recruit the first patient during the summer.

Thanks to the Vinnova grant received at the beginning of the year of almost SEK 5 million, Professor Sandra Lindstedt at Skåne University Hospital in Lund is preparing the start of a clinical trial together with Amniotics in which stem cell therapy will be used to repair damaged discarded donor lungs so that they become useful for lung transplantation. Results were recently presented from a preclinical lung transplant study conducted by Professor Lindstedt's group at Lund University and Skåne University Hospital. The study shows support for this concept and that treatment with PulmoStem significantly reduces the incidence of lung damage in connection with lung transplantation. The damaged lungs recovered following treatment with PulmoStem. The data also show a reduction in the incidence of Primary Graft Dysfunction (PGD), a serious transplant-related complication, while severe lung damage continued in untreated lungs. The effects of the lung transplant study were presented at the International Society for Heart and Lung Transplantation (ISHLT) 42nd Annual Meeting & Scientific Sessions, which was held April 27-30 in Boston, Massachusetts, USA. These important data pave the way for future studies. Lung transplantation is currently the only treatment for patients with severe endstage lung disease.

At the beginning of the quarter, Amniotics co-founder Niels-Bjarne Woods and his research group at Lund University's stem cell center published an article in EMBO Reports describing a novel mechanism of generating specific



Amniotics' cutting-edge project will soon enter clinical trials. Shortly after the end of the quarter, we received the green light to initiate the Phase I/II clinical trial using our unique drug candidate PulmoStem™ to heal lung damage. After the end of the quarter, new preclinical data were also presented demonstrating that PulmoStem reduces the incidence of lung damage in connection with lung transplantation.

blood cells, which may form the basis for novel treatment modalities for some of the most severe types of cancers. The study findings show that metabolic regulators can be used to direct blood development to produce cells such as Natural Killer (NK) cells and hematopoietic stem cells. We are now investigating how we can use and further develop this technology in our anti-cancer platform by generating standardized NK cells to attack and eliminate cancer cells. The results could ultimately address a great need in cancer care today.

We continue to see strong interest in engaging Amniotics as a contract manufacturer, and a collaboration would of course be an important addition to the funding of our clinical development program and our operational activities. To advance the company further in 2022, in April we chose to take out a short-term loan of SEK 15 million. We are currently evaluating various options for strengthening our financial position and securing the continued clinical development program.

In summary, we continue to deliver on our strategy. Amniotics' vision is to develop life-changing treatments and we are convinced that our unique drug candidate PulmoStem has the potential to improve life for people who suffer from serious pulmonary diseases. We are now extremely close to the next important milestone for Amniotics — starting the first clinical trial with a focus on COVID-19/ARDS.

Lund, May 2022 **Kåre Engkilde**, CEO

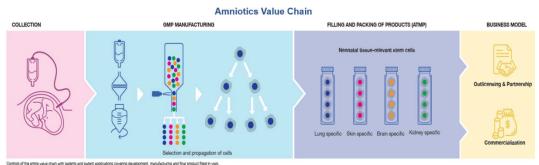
Amniotics in brief

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 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 lifechanging and regenerative treatments for

patients.

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.



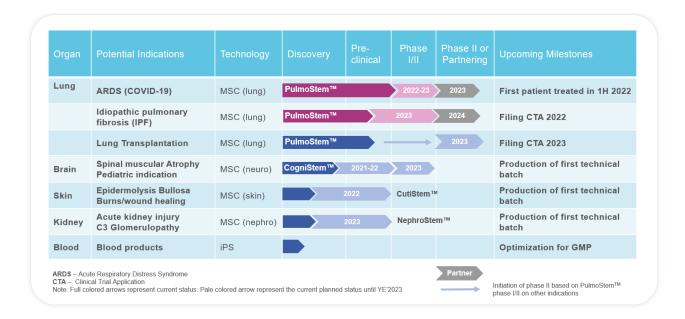
Amniotics has the capacity to work with other companies to add value through e.g.:

- 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 ready to be evaluated in a first 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.



Financial performance in summary

	Quai	Full-Year	
SEK 000	2022	2021	2021
Net sales	0	0	0
Operating result	-11,011	-12,501	-53,615
Cash flow from operating			
activities	-10,793	-22,476	-15,634
Cash position	32,768	22,533	43,981
Equity/assets ratio %	82	81	85
Earnings per share (SEK)	-0.69	-1.35	-3.34

Financial overview

Comprehensive result

Comprehensive result for the quarter was SEK -11 (-12.5) million, which corresponds to an improvement of SEK 1.5 million. Earnings per share, based on number of shares at end of the quarter, totaled SEK -0.69 (-1.35).

Expenses

Operating expenses for the first quarter totaled SEK 10.6 (12.1) million, a decrease of SEK 1.5 million. Expenses are allocated as follows: other external expenses SEK 5.9 (8.3) million, personnel costs increased by SEK 1 million due to increased number of employees and amounted to SEK 4.7 (3.7) million.

Investments

The company's net capital expenditure during the quarter amounted to SEK 0.3 (0.3) million, including SEK 0 (0.2) million attributable to property, plant, and equipment, and SEK 0.3 (0.1) million relating to investments in intangible assets.

Cash flow and financial position

Total shareholders' equity at end of the period was SEK 38.5 (29.7) 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 2.397 (3.211). The company's equity ratio at the end of the quarter was 82 (81) percent.

Cash and cash equivalents at the end of the period amounted to SEK 32.8 (22.5) 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 existing business plan.

Cash flow for the quarter was SEK -11.2 (22) million. Cash flow from financing activities totaled SEK -0.1 (-0.2) million.

Organization

The number of employees at the end of the

reporting period was 17, this an increase of 4 people compared with last year when it was 13 employees.

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 38.5 (29.7) 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

- Annual General Meeting, May 19th, 2022
- Interim Report Q2, Aug 16th, 2022
- Interim Report Q3, Nov 10th, 2022

The financial reports will be made available on the Amniotics website:

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

Annual General Meeting

The Annual General Meeting will be held on May 19, 2022.

Nomination Committee

In accordance with the resolution at the 2021 AGM, the Nomination Committee for the 2022 AGM has been appointed and announced. The Nomination Committee consists of: Christer Fåhraeus, representing Theope Seed Capital AB, Marcus Larsson, representing Deflexum AB and Fredrik Tiberg, representing LSCS Invest AB The company's chairman Peter Buhl Jensen, Chairman of the board of directors is co-opted in the nomination committee.

Certified Adviser

Amniotics Certified Adviser on First North is Redeye AB, certifiedadviser@redeye.se, telephone: +46 (0)8 121 576 90.

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, May 17th, 2022

Amniotics AB (publ)

Kåre Engkilde	Christer Fåhraeus	Anders Månsson
CEO	Board member	Board member
Peter Buhl Jensen	Marcus Larsson	Fredrik Tiberg
Chairman	Board member	<i>Board member</i>
Ingrid Atteryd Heiman Board member	Christopher Bravery Board member	

Financial Statements

Income statement in Summary

	Quarter 1		Full-Year
SEK 000	2022	2021	2021
Other operating income	36	3	50
Operating income	36	3	50
Operating expenses			
Other external costs	-5,850	-8,346	-35,294
Personnel costs	-4,709	-3,662	-16,056
Other operating costs	-59	-70	-162
Operating result before depreciation and amortization (EBITDA)	-10,582	-12,075	-51,615
Depreciation of tangible and intangible assets	-429	-426	-2,153
Operating result (EBIT)	-11,011	-12,501	-53,615
Net financial items	0	-0	-4
Result after financial items	-11,011	-12,501	-53,619
Taxes	0	0	0
Result for the period	-11,011	-12,501	-53,619

	Quarter 1		Full-Year
	2022	2021	2021
Earnings per share (SEK)*	-0.69	-1.35	-3.34
Number of shares**			
Weighted average for the period	16,066,033	9,244,000	14,349,755
Number of shares at start of period	16,066,033	9,244,000	11,166,500
Number of shares at end of period	16,066,033	9,244,000	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

	Quarter 1		Dec. 31
SEK 000	2022	2021	2021
Accepts			
Assets			0
Subscribed but not paid share capital			0
Fixed assets			
Intangible assets	4,679	4,023	4,392
Equipment and installations	7,294	8,947	7,724
Total fixed assets	11,973	12,970	12,116
Current assets			
Other receivables	2,055	1,353	1,991
Cash and bank balances	32,768	22,533	43,981
Total current assets	34,823	23,886	45,972
Total assets	46,796	36,856	58,088
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Shareholders' Equity and Liabilities			
Shareholders' equity			
Restricted equity			
Share capital	869	700	869
Reserve for development expenses	167	167	167
Non- restricted equity			
Share premium reserve	60,793	92,034	60,793
Accumulated loss including profit/loss for the period	-23,311	-63,214	-12,299
Total shareholders' equity	38,518	29,687	49,530
4,			,
Liabilities			
Liabilities to credit institutions, long-term	0	599	0
Current liabilities	8,278	6,570	8,558
Total liabilities	8,278	7,169	8,558
Total shareholders' equity and liabilities	46,796	36,856	58,088
Financial key ratios			
Shareholders' equity per share, SEK	2.397	3.211	3.083
Equity/assets ratio %	82	81	85
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Changes in equity

	Quart	Quarter 1	
SEK 000	2022	2021	Full Year 2021
Opening balance	49,530	42,186	42,186
Issue of shares	0	0	60,963
Loss for the period	-11,011	-12,501	-53,619
Equity at end of period	38,518	29,687	49,530

Cash Flow statement

	Quarter 1		Full Year
SEK 000	2021	2020	2021
Operating result	-11,011	-12,501	-53,616
Amortization and depreciation	429	426	2,153
Other, including non-cash items	-34	-114	-79
Cash flow from operating activities before change			
in working capital	-10,616	-12,189	-51,542
Change in working capital	-177	34,665	35,908
Cash flow from operating activities	-10,793	22,476	-15,634
Investing activities	-286	-271	-1,144
Cash flow after investing activities	-11,079	22,205	-16,778
Financing activities	-133	-182	-714
Rights issue	0	0	60,963
Change in cash and cash equivalents	-11,212	22,023	43,471
Cash and cash equivalents at the beginning of the			
period	43,981	510	510
	- /		
Cash and cash equivalents at the end of the period	32,768	22,533	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.

Amniotics



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