Amniotics

Report for the Second 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 CEmarked medical device, to collect amniotic fluid.

 Unique platform technology - the company 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 GMI production facility in Lund. This ensures accessibility and flexibility.

PulmoStem[™] entering clinical phase

April - June in brief

- Total revenues: SEK 0 (0).
- Operating profit (EBITDA): SEK -10.2 (-17.2) million.
- Result for the period: SEK -10.7 (-17.7) million.
- Earnings per share: SEK -0.66 (-1.11)
- Cash flow for the quarter: SEK -3.6 (13.6) million.
- Cash and cash equivalents at the end of the reporting period: SEK 29.1 (8.9) million.
- Equity/assets ratio as per the end of the reporting period: 65 (88) %.
- The company 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[™].
- Amniotics AB has taken out a short-term loan of SEK 15 million. The proceeds from the loan will be used to continue the development, and the existing operations in accordance with existing business plan until the end of 2022.
- Amniotics presented positive preclinical data on stem cell treatment for chemotherapy-induced peripheral neuropathy at ICRBE 2022. The results show that treatment with MSC selected for neural specificity (CogniStem[™]) have significant positive efficacy on chemotherapy-induced hearing loss and chemotherapy-induced neuropathic pain.

January - June in brief

- Total revenues: SEK 0 (0).
- Operating profit (EBITDA): SEK -21.6 (-30.2) million.
- Result for the period: SEK -21.7 (-30.2) million.
- Earnings per share: SEK -1.35 (-1.90).
- Cash flow for the quarter: SEK -14.8 (8.4) million.
- Amniotics received a grant of SEK 4,8 million from Sweden's Innovation Agency, Vinnova, together with Skåne University Hospital 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.

Other events after the end of the reporting period

 US Patent and Trademark Office (USPTO) has approved a patent application for the company's stem cell product PulmoStem[™].

CEO Statement

It is with great satisfaction that I can state that during second quarter we delivered real breakthroughs for Amniotics. During the quarter, we received approval for our first clinical study. Our business within contract manufacturing has been strengthened through new hires in the production team during the quarter. We have also done changes in our product portfolio for the coming year where we intend to prioritize the company's resources on PulmoStem[™] within the indications Covid-19/ARDS (Acute Respiratory Distress Syndrome) and lung transplantation as well as NK cells in oncology. This aims to optimize the company's capacity and financial resources in the areas where we see the greatest potential in the near term.

Our focus during the quarter has been the upcoming phase I/II study with PulmoStem - Amniotics lung-specific stem cell therapy developed for the treatment of lung diseases where inflammation and fibrosis are key factors, for example ARDS, covid-19 with or without ARDS and acute rejection of graft in case of lung transplantation. Covid-19-related ARDS is the first indication in our clinical development program for PulmoStem.

Patients with Covid-19 who become seriously ill may develop ARDS requiring intensive care. Unfortunately, there is a great deal of chronic morbidity in the aftermath of those affected by ARDS, even after moderate illness. Up to 10 percent have permanent problems. Today there is a lack of drugs with a satisfactory effect against ARDS triggered by Covid-19 and the treatment consists of a combination of symptom relief and preventive therapies. Due to the pandemic, ARDS has increased sharply. In Sweden and globally, Covid-19 is still a health problem with the development of new variants, increasing spread of infection and hospitalization. The burden on healthcare has affected our preparations for the planned phase I/II study on hospitalized Covid-19 patients at risk of developing severe ARDS. The study is our first clinical study in humans with the aim of investigating the safety and tolerability of intravenous dosing at different doses of PulmoStem.

During the quarter, we received approval from regulatory authorities in Sweden and United Kingdom to start the study, and during the summer we worked on completing the trial centres and producing product for the study. We expect to recruit the first patients in the near future and the results from the study are expected, as previously announced, in the second half of 2023.

The results from the study on Covid-19 patients will be important for further studies with PulmoStem in other lung and respiratory diseases, for example lung damage in connection with lung transplantation. The prognosis for lung transplant patients is poor and an estimated 30 percent develop the serious complication primary graft dysfunction (PGD). During the quarter, results from a preclinical lung transplantation study carried out by Professor Sandra Lundstedt's group at Lund



University and Skåne University Hospital were presented. It showed a statistically significant and medically relevant reduction in the number of PGD cases when treated with PulmoStem. We are now planning for a phase I/II study in 2023, in lung transplantation with the support of the planned clinical study in Covid-19 patients.

NK cell therapies (Natural Killer cells) have been shown in several clinical studies to be effective against hematological and solid tumours. We see great potential in the field, which is also the reason why NK cell therapies in oncology now are a part of our prioritized product portfolio. Amniotics have previously described a new method for generating hematopoietic stem cells (HSCs) and NK cells that may lead to new treatment approaches for some of the most serious forms of cancers.

In the cancer field, we presented promising new preclinical data for the treatment of chemotherapy-induced peripheral neuropathy (CIPN), a very common side effect of chemotherapy treatment, with mesenchymal stem cells at the ICRBE conference in Zurich in July. The results show the potential breadth of the use of CogniStem[™] as a treatment in conjunction with cancer therapy. The results are a clear validation of Amniotics platform and our therapeutic approach. And this will be further strengthened through development of our for-runner PulmoStem.

During the quarter, Amniotics has expanded with new employees, and strengthened our finances, to enable our intensive research work. We have an exciting autumn ahead of us and we feel well prepared for the challenges we face with the goal of being able to help seriously ill people to a better life.

Lund, August 2022 Kåre Engkilde

Amniotics in brief

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

Amniotics origin

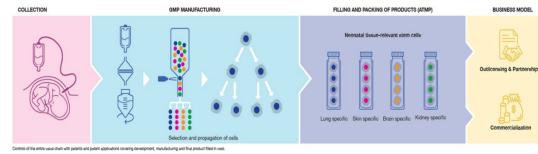
Amniotics was born out of the discovery of a novel source of stem cells in full-term amniotic fluid. Based on a decade of research at the internationally recognized Lund University Stem

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

Cell Center and Hospital, the company is pioneering the harvesting and propagation of tissue specific



Amniotics Value Chain

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[™])

innovative life-changing and regenerative treatments for patients.

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 is ready to be evaluated in a clinical study with a planned start during 2022. Amniotics strategy also includes being an active and attractive contract manufacturer of potent MSCs to external research programs in order 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

Amniotics Pipeline

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, 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 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 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.

Pipeline – current prioritized areas



Amniotics additional platform candidates

Technolog y Platform	Candidate	Indication	Discovery	Preclinical	Phase I	Phase II / partnering
(MSC)	PulmoStem™	Idiopathic pulmonary fibrosis (IPF)				
STEM CELLS (I	CogniStem™	Cisplatin induced periphereal neurophathy Atrophy (Brain)				
	NephroStem™	Acute kidney injury C3 Glomerulopathy				
EVs	CutiStem™	Epidermolysis Bullosa Burns/wound healing (Skin)				
ARDS – Acute Respiratory Distress Syndrome iPSC = induced pluripotent stem cell Evs = Extracellular vesicles					Completed Ongoing Planned	

Financial performance in summary

	Quarter 2			<u>Full year</u>	
(SEK 000)	2022	2021	2022	2021	Year
Net sales	0	0	0	0	0
Operating result	-10,604	-17,666	-21,616	-30,166	-53,615
Cash flow from operating					
activities	-12,705	-72,181	-23,499	-49,705	-15,634
Cash position	29,135	8897	29,135	8,897	43,981
Equity/assets ratio %	65	88	65	88	85
Earnings per share (SEK)	-0.66	-1.11	-1.35	-1.90	-3.34

Financial overview

Comprehensive result

Comprehensive result for the quarter was SEK -10.7 (-17.7) million, which corresponds to an improvement of SEK 7 million. Earnings per share, based on number of shares at end of the guarter, totaled SEK -0.66 (-1.11).

In the half year, the comprehensive result was SEK -21.7 (-30.2) million, which corresponds to an improvement of SEK -8.5 million. Earnings per share, based on number of shares at end of the period, totaled SEK -1.35 (-1.90).

Expenses

Operating expenses for the second quarter totaled SEK 10.7 (17.7) million, a decrease of SEK 7 million. Other external costs decreased by SEK 6.3 million and amounted to SEK 6.5 (12.8) million. The reduction is mainly due to the fact that in 2021, the company had costs of approx. SEK 6 million when listing on Nasdaq First North Growth Market. Personnel costs amounted to SEK 3.7 (4.4) million, a decrease of SEK 0.7 million as a result of, among other things, lower recruitment costs during the second quarter of 2022. Financial costs increased by SEK 73 thousand, due to taking out a short-term loan, and amounted to SEK 77 (4) thousand.

Operating expenses for the half year amounted to SEK 21.8 (30.2) million, a decrease of SEK 8.4 million. Other external costs amounted to SEK 12.3 (21.1) million, a decrease of SEK 8.8 million. A large part of the reduction is due to the costs in connection with the IPO in 2021 of SEK 6 million, as well as lower consulting fees. Personnel costs increased by SEK 0.3 million as a result of four additional employees compared to the previous year and amounted to SEK 20 (16) million.

Investments

The company's net capital expenditure during the quarter amounted to SEK 0.7 (0.4) million, including SEK 0.3 (0.1) 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 27.8 (71.1) 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 1.733 (4.485). The company's equity ratio at the end of the quarter was 65 (88) percent.

Cash and cash equivalents at the end of the period amounted to SEK 29.1 (8.9) 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 -3.6 (-13.6) million. Cash flow from financing activities totaled SEK -0.1 (-0.2) million.

Cash flow for the half year amounted to SEK 43.5 (-5.5) million. Cash flow from financing activities during the period amounted to SEK 9.8 (58.9) million.

Organization

The number of employees at the end of the reporting period was 20, this an increase of 4 people compared with previous year when it was 16 employees. During the second quarter, three people have been employed in manufacturing to ensure products for the company's future studies.

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 29.1 (8.9) 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. Amniotics entered into liquidity providing agreement regarding a liquidity guarantee for Amniotics shares.

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

Interim Report Q3, Nov 10th, 2022

The financial reports will be made available on Amniotics website:

https://www.amniotics.com/investors/financialreports/

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 Kåre Engkilde, CEO Phone: +46 (0)723 27 85 20 Email: ke@amniotics.com

Johny Humaloja, CFO Phone: +46 (0)735 06 68 56 Email: jh@amniotics.com

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, August 16th, 2022

Amniotics AB (publ)

Kåre Engkilde CEO Ingrid Atteryd Heiman Board member Anders Månsson *Board member*

Peter Buhl Jensen *Chairman* Marcus Larsson *Board member* Fredrik Tiberg Board member

Christopher Bravery *Board member*

Financial Statements

Income statement in Summary

	Quarter 2		H	Full-Year	
SEK 000	2022	2021	2022	2021	2021
Other operating income	50	24	86	28	50
Operating income	50	24	86	28	50
Operating expenses					
Other external costs	-6,463	-12,787	-12,313	-21,132	-35,294
Personnel costs	-3,696	-4,426	-8,404	-8,088	-16,056
Other operating costs	-48	-49	-108	-119	-162
Operating result before depreciation and amortization (EBITDA)	-10,157	-17,238	-20,739	-29,311	-51,615
Depreciation of tangible and intangible assets	-448	-428	-877	-855	-2,153
Operating result (EBIT)	-10,605	-17,666	-21,616	-30,166	-53,615
Net financial items	-77	-4	-77	-4	-4
Result after financial items	-10,682	-17,670	-21,693	-30,170	-53,619
Taxes	0	0	0	0,	0
Result for the period	-10,682	-17,670	-21,693	-30,170	-53,619

	Quarter 2		<u>H1</u>	Full-Year	
	2022	2021	2022	2021	2021
Earnings per share (SEK)*	-0.66	-1.11	-1.35	-1.90	-3.34
Number of shares**					
Weighted average for the period	16,066,033	12,967,163	16,066,033	12,658,049	14,349,755
Number of shares at start of period	16,066,033	12,935,000	16,066,033	11,166,500	11,166,500
Number of shares at end of period	16,066,033	15,861,830	16,066,033	15,861,830	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

	June	Dec. 31	
SEK 000	2022	2021	2021
A (-			
Assets			
Subscribed but not paid share capital	0	58 000	0
Fixed assets			
Intangible assets	5 004	4 139	4 392
Equipment and installations	7 250	8 778	7 724
Total fixed assets	12 254	12 917	12 116
Current assets			
Other receivables	1 740	1 069	1 991
Cash and bank balances	29 135	8 897	43 981
Total current assets	30 875	9 966	45 972
Total assets	43 129	80 883	58 088
Shareholders' Equity and Liabilities			
Shareholders' equity			
Restricted equity			
Share capital	869	858	869
Reserve for development expenses	167	167	167
Non- restricted equity			
Share premium reserve	0	58 963	60 793
Accumulated loss including profit/loss for the period	26 800	11 149	-12 299
Total shareholders' equity	27 836	71 137	49 530
Liabilities			
Liabilities to credit institutions, long-term	0	5515	0
Current liabilities	15 293	4 231	8 558
Total liabilities	15 293	9 746	8 558
Total abarabaldaral aguity and list litica	40,400	00.000	F0 000
Total shareholders' equity and liabilities	43 129	80 883	58 088
Financial key ratios			
Shareholders' equity per share, SEK	1,733	4,485	3,083
	.,. 50	.,	-,

65

88

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

Equity/assets ratio %

85

Changes in equity

	<u>H1</u>	Full Year	
SEK 000	2022	2021	<u>2021</u>
Opening balance	49,530	42,186	42,186
Issue of shares	0	59,121	60,963
Loss for the period	-21,693	-30,170	-53,619
Equity at end of period	27,836	71,137	49,530

Cash Flow statement

	Quarter 1		<u>H1</u>		<u>Full</u> Year	
SEK 000	2022	2021	2022	2021	2021	
Operating result	-10,604	-17,666	-21,616	-30,166	-53,616	
Amortization and depreciation	448	428	877	855	2,153	
Other, including non-cash items	-20	43	-54	-67	-79	
Cash flow from operating activities before change in						
working capital	-10,176	-17,195	-20,793	-29,378	-51,542	
Change in working capital	-2,529	-54,986	-2,706	-20,327	35,908	
Cash flow from operating activities	-12,705	-72,181	-23,499	-49,705	-15,634	
Investing activities	-729	-376	-1,015	-647	-1,144	
Cash flow after investing activities	-13,434	-72,557	-24,514	-50,352	-16,778	
Financing activities	9,801	-200	9,668	-382	-714	
Rights issue	0	59,121	-,	59,121	60,963	
Change in cash and cash equivalents	-3,633	-13,636	-14,846	8,387	43,471	
Cash and cash equivalents at the beginning of the						
period	32,768	22,533	43,981	510	510	
Cash and cash equivalents at the end of the period	29,135	8,897	29,135	8,897	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

Amniotics AB (publ)

Medicon Village, Scheelevägen 2 SE-223 63 Lund Sweden

www.amniotics.com

