# Amniotics

# **Report for the First 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 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 i vials takes place in the company's own GM production facility in Lund. This ensures accessibility and flexibility.

# Clinical study completed

## January - March in brief

- Total revenues: SEK 0 (0).
- Operating profit (EBITDA): SEK -10.8 (-10.6) million.
- Result for the period: SEK -11.8 (-11) million.
- Earnings per share: SEK -0.10 (-0.69).
- Cash flow for the quarter: SEK 31.2 (-11.2) million.
- Cash and cash equivalents at the end of the reporting period: SEK 40.3 (32.8) million.
- Equity/assets ratio as per the end of the reporting period: 17 (82) %.
- At the company's extraordinary general meeting on February 17, 2023, the meeting decided to approve the board's decision of January 17, 2023, on the rights issue of a maximum of 144,596,970 units.
- Amniotics carried out a preferential rights issue which brought the company SEK 25.3 million before issue costs and offsetting and repayment of outstanding bridging loans. Remaining loans after set-off and repayment amount to SEK 4.2m.

### Events after the quarter

 Gerton Jönsson was appointed as the new CFO. Gerton Jönsson takes office on May 2, 2023.

## Other events during the quarter

The company received positive information about the safety data for PulmoStem<sup>™</sup> in a clinical study. The company announced that safety has been established in the second cohort of the completed Phase Ib clinical trial investigating the lung-specific stem cell therapy PulmoStem<sup>™</sup> in hospitalized patients with severe respiratory infections caused by COVID-19, RSV or other viral infections.

# **CEO** Statement

### **Clinical study completed**

In the first quarter of 2023 Amniotics completed the first clinical phase I study of PulmoStem in humans. The study included patients with severe lower respiratory tract infections caused by viruses, including Covid-19. Positive data from the safety committee's evaluation could be reported. That safety has been established at relevant dose levels is of great value for the company's continued development program of PulmoStem. The final report for the study is expected early in the third quarter of 2023. In parallel, the company has already begun analysis of possible improvements to the practical aspects regarding the preparation, handling and administration of PulmoStem. This type of product optimization is an important part of product development, where we particularly focus on the usability of PulmoStem in lung transplantation, which we see as a promising indication area. Discussions regarding a continuation in the field of lung transplantation are ongoing with an interested research clinic.

The company carried out a rights issue during the first quarter, which was subscribed to 70 percent. Of course, the company had hoped for a higher subscription rate, but considering the climate on the capital market, we are still satisfied with the outcome. The strategic reorientation to actively seek collaboration partners for our development projects instead of running the projects themselves as before led to the company's carrying out a major reorganization of the company. It began in the fourth quarter of 2022 and has continued according to plan. The company is now significantly better equipped to meet the demanding market conditions. We have also been able to strengthen the research and development organization with a specialist in the iPSC area (general stem cells), which is connected to the Amniotics NK cell project. In this context,



it can be mentioned that the company worked on completing the necessary cooperation agreements for the EU-supported consortium in the development of new NK cell-based therapies that Amniotics leads. With agreements in place, the project has now officially started since the first of April 2023. Total support that the consortium receives is EUR 3.8M and the project runs over three years. In addition to Amniotics, the University of Copenhagen, Lund University and Medizinische Hochschule Hannover are included.

In summary, the quarter has contained a number of strategic successes for the company, and we are working further to refine these by focusing resources on research and development towards our priority areas. The company has also increased efforts to seek strategic partners for business development.

Lund, April 2023 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

- Lung (PulmoStem™)
- Brain (CogniStem™)
- Kidney (NephroStem™)
- Skin (CutiStem<sup>™</sup>)

### 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

**Amniotics Value Chain** 



Amniotics is a biopharma

cell specialist

Woods discovered a new type of stem cells in amniotic fluid that has properties for applications in regenerative medicine.

Niels-Bjarne

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 newborn 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;

providing the very best stem cells for medical applications. Amniotics is devoted to developing innovative life-changing 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<sup>™</sup>). With the results from Amniotics<sup>™</sup> 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<sup>™</sup>, 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 two patent families attributable to the Company's MSC products intended for use in several treatments / indications. In addition, the Company has filed an additional 33 patent applications.

### 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<sup>™</sup>), brain indications (CogniStem<sup>™</sup>), dermatological indications (CutiStem<sup>™</sup>) and kidney-specific indications (NephroStem<sup>™</sup>). Amniotics lung-specific product PulmoStem<sup>™</sup> 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<sup>™</sup>, Amniotics intends to seek a partner for out licensing the products / technology for the development of treatment for relevant lung diseases.

#### Pipeline – Focus areas

Plat	form	Candidate	Indication	Discovery	Preclinical	Phase I	Phase II / Partnering	Upcomming milestones
W	sc)	PulmoStem ™	ARDS (COVID-19)			>		Readouts in H2 2023
STEM CELLS (MSC)	CEL (MS	PulmoStem ™	Lung Transplantation					
-NK-	cells (iPSC)	AMNI- NK003	Oncology					GMP Optimization, H2 2023

#### Amniotics other platform candidates

Technolog y Platform	Candidate	Indication	Discovery	Preclinical	Phase I	Phase II / partnering
(MSC)	PulmoStem™	Idiopathic pulmonary fibrosis (IPF)		>		
STEM CELLS (	CogniStem™	Cisplatin induced periphereal neurophathy Atrophy (Brain)				
STEM	NephroStem™	Acute kidney injury C3 Glomerulopathy				
EVs	CutiStem™	Epidermolysis Bullosa Burns/wound healing (Skin)	$\rightarrow$			
	lespiratory Distress Syndr pluripotent stem cell lar vesicles	ome			Completed Ongoing Planned	

### Financial performance in summary

	Quarter 1		Full Year
(SEK 000)	2023	2022	2022
Net sales	0	0	0
Operating result	-11,241	-11,011	-46,693
Cash flow from operating activities	22,166	-10,793	-46,184
Cash position	40,306	32,768	9,104
Equity/assets ratio %	17	82	5
Earnings per share (SEK)	-0.10	-0.69	-2.99

# **Financial overview**

#### **Comprehensive result**

Comprehensive result for the quarter was SEK -11.8 (-11) million, which corresponds to a decrease of SEK 0.8 million. Earnings per share, based on the number of shares at the end of the quarter, amounted to -0.10 (-0.69) SEK.

#### Expenses

Operating expenses for the quarter amounted to SEK 11.6 (11) million, which corresponds to an increase of SEK 0.6 million. Other external expenses decreased by SEK 1.7 million and amounted to SEK 4.2 (5.9) million. The reduction is mainly due to the fact that the company's production costs and costs for raw materials have been reduced compared to the previous year. Personnel costs amounted to SEK 6.7 (4.7) million, an increase of SEK 2 million as a result of the company having more employees. Financial costs increased by SEK 0.6 million, as a result of taking out a short-term loan, and amounted to SEK 611 thousand (0).

#### Investments

The company's net investments during the quarter amounted to SEK 0.8 (0.3) million, of which SEK 0.7 (0) million attributes to tangible fixed assets and SEK 0.1 (0.3) million related to investments in intangible assets.

#### Cash flow and financial position

Cash flow for the guarter amounted to SEK 31.2(-11.2) million. Cash flow from financing operations amounted to SEK 9.2 (-0.1) million. Total equity at the end of the period amounted to SEK 10.2 (38.5) million after taking into account the guarter's results. Equity per share (based and after dilution) based on the number of outstanding shares at the end of the period was SEK 0.087 (2.397). At the end of the quarter, the company's equity ratio was 17 (82) percent. During the guarter, the Company carried out a rights issue and the total was subscribed 74,395,035 units supported by unit rights, corresponding to 51.4 percent of the Rights Issue. In addition, it was signed.

8,297,907 units without the support of unit rights, corresponding to approximately 5.7 percent of the rights issue, and 18,524,938 units, corresponding to 12.8 percent, were subscribed by underwriters. The rights issue was thus 70 percent subscribed, and through the rights issue Amniotics receives SEK 25.3 million before issue costs as well as offsetting and repayment of outstanding bridging loans to Fårö Capital AB and Modelio Equity AB (publ). After the rights issue and completion of set-off, Modelio's remaining loan amounts to a capital amount of SEK 4.0 million, while Fårö Capital's loan of SEK 5 million is settled in its entirety. In June 2023, the Company can receive additional liquid of a maximum of SEK 69 million from warrants, series TO 2 that were issued in the rights issue.

During the quarter, the company received the first partial payment of the granted EIC-Pathfinder grant of SEK 32 million. During April, SEK 25.2 million of the amount received will be paid to other participants in the consortium. This grant will finance the development of improved Natural Killer (NK) cells derived from iPS cells where the consortium is led by Amniotics AB. Other participants are Lund University, Medizinische Hochschule Hannover and the University of Copenhagen.

Management and the board continuously review the capital needs and requirements to be able to continue running the business.

#### Organization

The number of employees at the end of the reporting period was 14, this an decrease of 3 employees compared with previous year when it was 17 employees.

#### Share capital

The company carried out a rights issue during the quarter and the number of shares in Amniotics increased by 101,217,880 shares from 16,066,330 shares to 117,284,210 shares with a quota value of SEK 0.05409. The share capital increased by SEK 5,474,787.970577 from SEK 869,013.954998 to SEK 6,343,801.925575.

# 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 amounted to SEK 40.3 (33) million at the end of the quarter. The company has carried out a rights issue of SEK 25.3 million during the first quarter of 2023. 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 117.284.210. 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, 22 May 2023
- Half-year report Q2 2023, 18 Aug 2023
- Interim report Q3 2023, 10 Nov 2023

Financial reports will be made available on Amniotics website:

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

#### Annual general meeting

The annual general meeting will be held on 22 May 2023. The time and place will be announced later.

#### Nomination committee

In accordance with the decision at the 2022 AGM, the Nomination Committee for the 2023 AGM has been appointed. The nomination committee consists of: Andreas Herbst, representing Parimus Invest AB, Marcus Larsson, representing Deflexum AB and Fredrik Tiberg, representing LSCS Invest AB. The company's chairman Peter Buhl Jensen, chairman of the board, is co-opted in the nomination committee.

#### For further information, please contact Marcus Larsson, CEO

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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 5<sup>th</sup>, 2023

Amniotics AB (publ)

Marcus Larsson CEO & board member Peter Buhl Jensen Chairman

Christopher Bravery Board member Fredrik Tiberg Board member Ingrid Atteryd Heiman Board member

# **Financial Statements**

# Income statement in Summary

	Quarter 1		Full Year
SEK 000	2023	2022	2022
Other operating income	316	36	553
Operating income	316	36	553
Operating expenses			
Other external costs	-4,161	-5,850	-26,622
Personnel costs	-6,655	-4,709	-18,507
Other operating costs	-255	-59	-324
Operating result before depreciation and amortization (EBITDA)	-10,755	-10,582	-44,900
Depreciation of tangible and intangible assets	-486	-429	-1,793
Operating result (EBIT)	-11,241	-11,011	-46,693
Net financial items	-611	0	-1,353
Result after financial items	-11,852	-11,011	-48,046
Taxes	0	0	0
Result for the period	-11,852	-11,011	-48,046

	Quarter 1		Full Year	
	2023	2022	2022	
Earnings per share (SEK)*	-0.62	-0.69	-2.99	
Number of shares*				
Weighted average for the period	26,188,118	16,066,033	16,066,033	
Number of shares at start of period	16,066,033	16,066,033	16,066,033	
Number of shares at end of period	117,284,210	16,066,033	16,066,033	

\* Based on number of shares at end of period

	Qu	<u>31 Dec</u>	
SEK 000	2023	2022	202
Assets			
Fixed assets			
Intangible assets	6,670	4,679	6,55
Equipment and installations	6,987	7,294	6,79
Total fixed assets	13,657	11,973	13,35
Current assets			
Other receivables	5,799	2,055	6,17
Cash and bank balances	40,306	32,768	9,10
Total current assets	45,843	34,823	15,28
Total assets	59,500	46,796	28,63
	59,500	40,750	20,03
Shareholders' Equity and Liabilities			
Shareholders' equity			
Restricted equity			
Share capital	6,344	869	86
Reserve for development expenses	167	167	16
Non- restricted equity			
Share premium reserve	75,938	60,793	
Accumulated loss including profit/loss for the period	-72,198	-23,311	44
Total shareholders' equity	10,251	38,518	1,48
Liabilities			
Current liabilities	49.249	8.278	27,14
Total liabilities	59,500	8,558	27,14
Total shareholders' equity and liabilities	59,500	46,796	28,63

# Balance sheet in Summary

## **Financial key ratios**

Shareholders' equity per share, SEK	0.087	2.397	0.092
Equity/assets ratio %	17	82	5

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

# Changes in equity

	Qua	rter 1	Full Year	
SEK 000	2023	2022	2022	
Opening balance	1,484	49,530	49,530	
Issue of shares	20,619	0	0	
Loss for the period	-11,852	-11,011	-48,046	
Equity at end of period	10,251	38,518	1,484	

## **Cash Flow statement**

	Quarte	Full Year	
SEK 000	2023	2022	2022
Operating result	-11,241	-11,011	-46,693
Amortization and depreciation	486	429	1,324
Other, including non-cash items	-238	-34	-662
Cash flow from operating activities before change in			
working capital	-11,010	-10,616	-46,031
Change in working capital	33,176	-177	-3,255
Cash flow from operating activities	22,166	-10,793	-42,776
Investing activities	-792	-286	-1,360
Cash flow after investing activities	-20,011	-11,079	-44,136
Financing activities	-5,851	-133	14,469
Rights issue	15,679	0	0
Change in cash and cash equivalents	-31,202	-11,212	-20,369
Cash and cash equivalents at the beginning of the			
period	9,102	43,981	43,981
Cash and cash equivalents at the end of the period	40,306	32,768	23,612

# 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.



"Finansieras av Europeiska unionen. De åsikter och åsikter som framförs är dock endast författarens/författarnas och återspeglar inte nödvändigtvis Europeiska unionens eller Europeiska innovationsrådets åsikter. Varken Europeiska unionen eller den beviljande myndigheten kan hållas ansvariga för dem."

# Amniotics

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