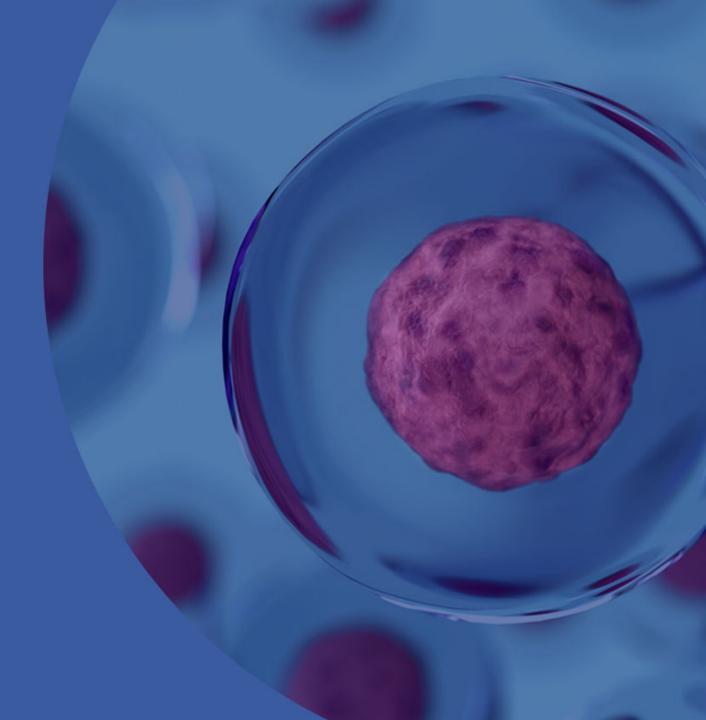
# **Amniotics**

**Management Presentation** 



# **Executive summary**



- Biopharma company developing a broad pipeline of unique stem cell therapeutics The technology is broadly applicable to major disease markets:
  - Respiratory (Lung); Neurodegenerative (Brain); Nephrology (kidney); Dermatology (Skin)
  - o The product PulmoStem™ is focused on COVID-19 related ARDS¹ is planned to start in H2 '2021, IPF² clinical trial in patients is planned to start in H2'2022 and Lung transplant in 2023
  - Controls the whole manufacturing value chain with patents covering the entire process from collection device to filling of vials



- The unique technology is based on collecting Mesenchymal Stem Cells (MSC) from amniotic fluid, followed by a patent-protected enhancement of the MSCs into several kinds of tissue (or organ) specific pharmaceutical products
  - Tissue specific MSC are believed to have improved properties for diseases affecting the organ relevant for the type of MSC
  - Neonatal or embryonic derived stem cells are thought to be of higher quality than those derived from adults, but sourcing
    in high enough quantity has been challenging (prior to new technologies such as the one from Amniotics)
  - Amniotic-fluid based sourcing from planned C-sections provides ample supply volumes combined with high ethical standards



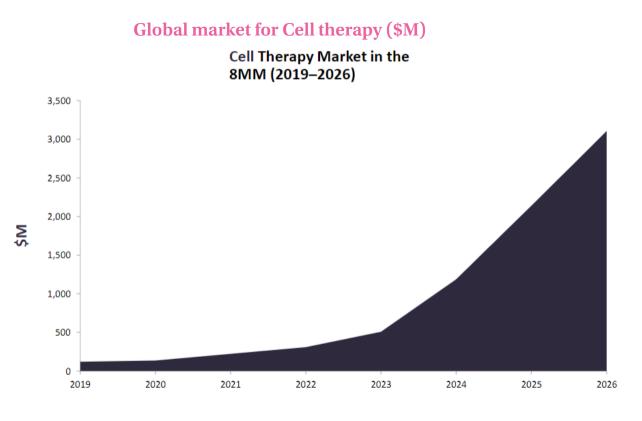
- Few drugs approved, but global cell therapy market is growing fast: Predicted to reach \$3,1 billion in 2026<sup>3</sup>
- Swedish listing planned for June 2021 to access capital for expansion and to attain a market-based valuation
  - 1) ARDS Acute Respiratory Distress Syndrome
  - 2) IPF Idiophatic Pulmonary Fibrosis
  - 3) Source: "Regenerative Medicine in Pharma Global data 2020"



# Global Cell therapy Market: Early stage but fast growing<sup>1)</sup>

### The cell therapy market is valued at \$121M in 2019 in the 8MM and is forecast to reach \$3.1B by 2026

- Cell therapies have the potential to change the treatment landscape due to their curative potential for numerous diseases
- With only a few therapies actually approved and, on the market, cell therapies are still early days, but the field is expected to grow in the coming years due to clinical successes that will encourage investments
- Global data predict that the cell therapy space will reach \$3.1B in 2026



<sup>1)</sup>Source: "Regenerative Medicine in Pharma Global data 2020"

Cell therapies include: embryonic stem cells (ESCs), induced pluripotent stem cells (iPSCs), nuclear transfer embryonic stem cells (ntESCs), parthenogenetic embryonic stem cells (pES), hemapoetic stem cells (HSCs), Mesenchymal Stem cells (MSCs), neural stem cells (NCs), epithelial stem cells & Immune cell therapy

8MM: US, France, Germany, Italy, Spain, UK, Japan and China

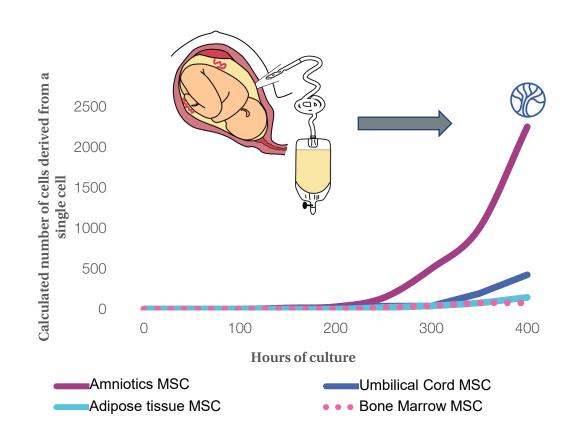


# Differentiated technology with many advantages

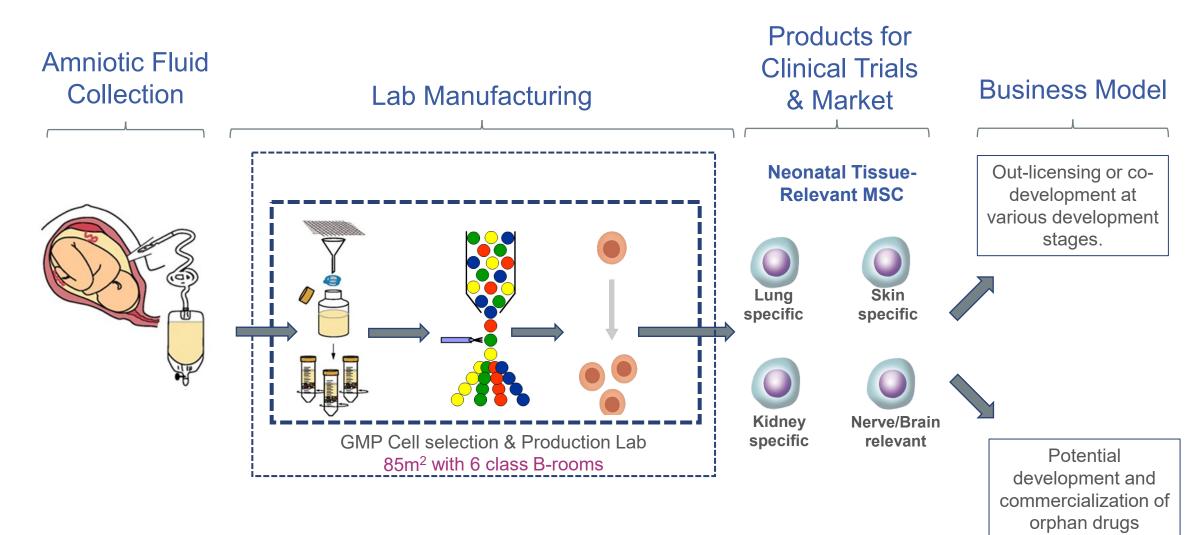
### **Background**

Pre-natal infants deposit MSC into the Amniotic Fluid from tissue in contact with the fluid - this source can produce an array of different neonatal tissue-relevant MSC: lung, skin, kidney, and brain MSC

- Tissue relevant MSC are believed to potentially lead to better therapeutic effects
- Amniotics MSC are collected from Term Amniotic Fluid (TAF) from planned C-sections using a patented, CE-approved medical device1. TAF is otherwise considered a medical waste product
- The high quality of the cells allow much more pronounced expansion
- The yield of stem cells attained in TAF is considerably higher than that derived from other sources. It is estimated that each donation can yield enough stem cells for >6000 patients and it is also ethically accepted



# **Technology and Process**



Control of the whole manufacturing value chain with patents covering the whole process from device to filling of vials



# Amniotics has its own Certified GMP<sup>1</sup> facility for production

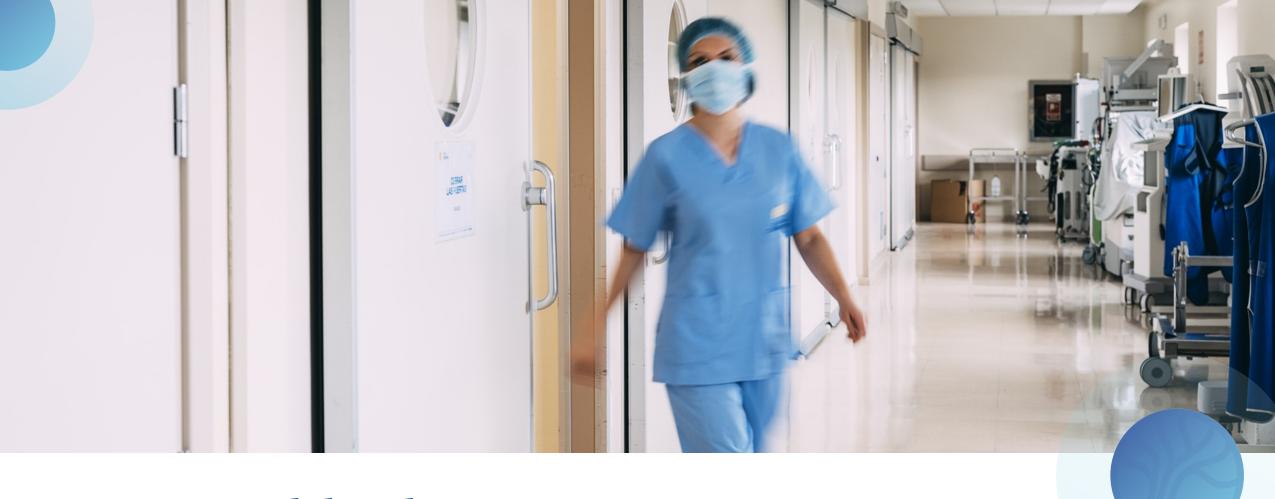
- In 2020 Amniotics built its own GMP production facility which was approved by the Swedish Medical Products Agency in November 2020
- The GMP facility is 85m<sup>2</sup> and has 6 class B rooms and is fully equipped with "state of the art" equipment for producing Advanced Therapy Medicinal Products (ATMPs)
- In addition, Amniotics has two QC labs to control the product and sterility
- Amniotics also has its own storage facility for finished product with freezers at -80° C and -150° C



Having its own GMP facility helps speed up the development time and Amniotics will be able to retain manufacturing rights when products are out-licensed. In addition, Amniotics offers CDMO<sup>2</sup> services to Universities, Hospitals, and the Biopharmaceutical industry with a focus on GMP compliant manufacture of ATMPs

<sup>1)</sup> GMP stands for Good Manufacturing Practice, which means that quality standards are met for producing product for human use

<sup>2)</sup> CDMO - Contract Development and Manufacturing Organization



**Business Model and Aspirations** 

### **Business Model for Amniotics**

- Amniotics business rests on know-how and IP around a novel way to harvest and manufacture tissue-specific MSC, and the identification of pharmaceutical development projects that match the particular MSC
- 1) Main business follow a typical biotech model build pipeline and strike lucrative partnership deals. This is a higher risk higher reward model
- Amniotics can control major portions of the value chain depending on the particular type of disease, and resources needed for clinical development licensing to pharma at different stages depending on the project. This is important to maximize risk-adjusted returns, and to control capital investment and business risk

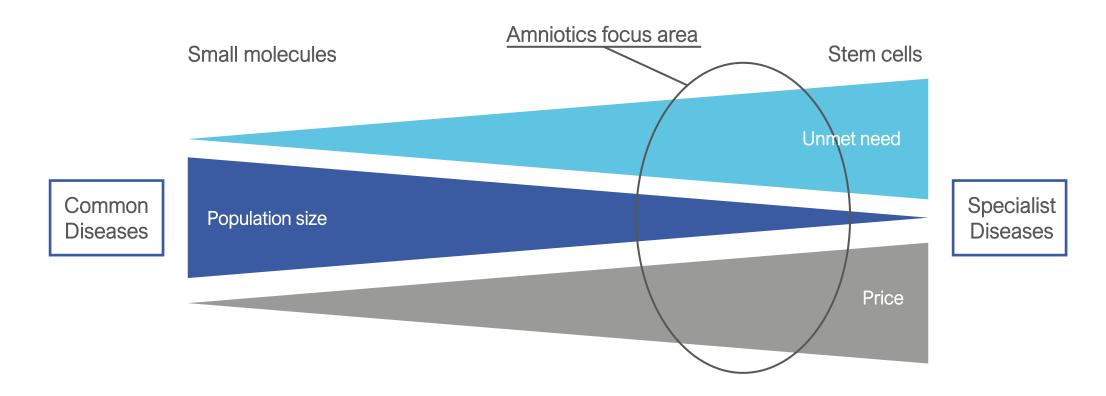


### Initial business plans are:

- For lung diseases: To start clinical development programs in several indications with the aim of out-license after Phase I/II For a selected opportunity Amniotics will evaluate partnering at a later stage after clinical Proof of Concept
- For Neuro indications: To start clinical development programs and out-license after Phase I/II
- 2) Amniotics secondary business opportunity is specialty manufacturing service. This is a lower risk, but lower reward model

# Amniotics will target niche indications with high unmet need

Amniotics is developing stem cell-based therapies for the treatment of patients with serious chronic diseases in areas of high unmet medical need. Targeting small, highly defined patient groups with very high unmet medical needs allows for demonstration of cost-effectiveness, even with high priced interventions<sup>1</sup>



# **Pipeline**

Organ	Indication	Technology	Disco-very	Pre- clinical	Phase I/II	Phase II or Part- nering	Upcoming Milestones
Lung	ARDS (COVID-19)	MSC (lung)	PulmoStem™		2021-22	2022	Filing CTA 1H 2021
	Idiopathic pulmonary fibrosis (IPF)	MSC (lung)	PulmoStem™		2022-23	2023	Filing CTA 2H 2022
	Lung Transplantation	MSC (lung)	PulmoStem™	_	<b></b> )	2022-23	Filing CTA 2023
Brain	Spinal muscular Atrophy Paediatric indication	MSC (neuro)	CogniStem	2021-22	2023		Production of first technical batch
Skin	Epidermolysis Bullosa Burns/wound healing	MSC (skin)		2023	CutiStem™	Л	Production of first technical batch
Kidney	Acute kidney injury C3 Glumerulopathy	MSC (nephro)		2023	NephroSte	m™	Production of first technical batch
Blood	Blood products	iPS					Optimization for GMP

Partner

Initiation of phase II based on PulmoStem™ phase I/II on other indications



# **Competition/Peers**

- Three relevant peers have been idendified all listed on U.S. Nasdaq, active in drug development based on stem cells (MSC)
- Overall these peers currently have more mature pipelines than Amniotics. However, the technology platform of Amniotics appear to have higher long-term potential. Amniotics pipeline is moving into phase I/II trials and Pulmostem™ for COVID19 could have results during 2022
- Athersys and Pluristem valuations are ~4-9x Amniotics estimated valuation of SEK 400M (incl IPO proceeds)







#### Market Cap

**Pipeline** 

**Technology** 

### \$1.1B

### A portfolio of Phase 3 product candidates including:

### Remestemcel-L ARDS (announced \$1.3B partnership)

 RYONCIL for pediatric and adult steroid-refractory acute graft versus host disease

deal w/ Novartis November 2020)

 REVASCOR® for advanced chronic heart failure

from bone marrow and adipose

Mesoblast has a proprietary technology platform for generative medicine based on adult mesenchymal stem cells derived

tissue

#### \$0.35B

#### A broad range of clinical programs where

- MultiStem cell therapy for the treatment of myocardial infarction is in Phase III is the treatment closest to commercial stage.
- Multistem is in late stage development for ARDS/ COVID19

MultiStem®, a patented, adult-derived "off-the-shelf" stem cell therapy platform, for disease indications in areas of neurological, inflammatory & immune, and cardiovascular disease areas

#### \$0.14B

Clinical programs are in the final stages of development.

- Critical Limb Ischemia (CLI); study did not meet primary endpoint (Dec 2020)
- Muscle regeneration following hip fracture surgery
- Acute Radiation Syndrome (ARS)

Using placental cells and a proprietary 3D technology platform to develop cell therapies





# **Milestones - Pipeline and Corporate Development**

Timing	Event	
1H' 2019	Directed share issue – SEK 20m	✓
1H' 2020	Directed share issue – SEK 25m	✓
1H' 2020	CE Mark of TAF Collection device	$\checkmark$
1H' 2020	Manufacture of first PulmoStem batch	$\checkmark$
2H' 2020 October	Certification for the GMP production & Tissue Establishment facility	$\checkmark$
2H' 2020 November	Swedish MPA granted Amniotics a Manufacturing Authorization and GMP Approval	✓
2H' 2020 December	Directed share issue <sup>1</sup> – SEK 37,8m	✓



Amniotics Certified GMP production facility in Lund

# **Upcoming Milestones 2021 - 2023**

Milestone	2021
Filing CTA Phase I/II ARDS/COVID-19	1H
IPO and listing First North	1H
First patients treated in ARDS/ COVID-19	1H
Filing for Orphan indication IPF in EU	1H
Research collaboration on CogniStem™	1H
Orphan indication outcome for IPF in EU	2H
Last patient treated in ARDS/ COVID-19	2H
Production of first technical batch for Cognistem™	2H
Filing for Orphan indication in US	2H

Milestone	2022
Phase I/II report in ARDS/COVID-19	1H
Regulatory advise ARDS/COVID-19	1H
Orphan indication outcome for IPF in US	1H
Filing CTA Phase I/II for Pulmostem™ in IPF	2H
Production of first technical batch NephroStem™	2H
Lung Transplant regulatory advise	2H
Potential Licensing Agreement PulmoStem™ ARDS/COVID-19	2H

Milestone	2023
Filing CTA for Phase II in Lung Transplant	1H
Production of first clinical batch for Cognistem™	1H
Filing CTA Phase I/II for Cognistem™	2H
Phase I/II report for Pulmostem™ in IPF	2H



# Management Team - Experienced and Qualified

### Management



Kåre Engkilde CEO

- MSc in Chemical Engineering and Biotechnology from Denmark's Technical University, followed by a PhD in Immunology at Københavns Universitet, Denmark
- Joined in 2019
- Previously at Novo Nordisk, LEO Pharma, Bioneer, Agilent Technologies



Jan Talts

- PhD in Animal Physiology, Uppsala University, Sweden
- Joined in 2017
- Previously at Xintela AB, Skåne University Hospital, University of Copenhagen, Denmark, Lund University, Sweden and Max-Planck-Institut for Biochemistry, Germany



Helle Størum
Head of Business
Development

- MSc in Economic, University of Southern Denmark, Denmark
- Joined in 2020
- Previously Director of Strategy and Business Development at Pharmacosmos, Director at Zealand Pharma and Section Head Market Research at H Lundbeck



Jonas Lundahl
Director Clinical/Regulatory
Affairs

- PhD in Clinical Pharmacology, University of Gothenburg, Sweden
- Joined in 2020
- Previously Sr Medical Science Lead at LEO Pharma, Chief Clinical Officer at Prophylix Pharma and specialist at H.Lundbeck

# **Board of Directors following AGM in April 2021**

### Re-elected members



Christer Fåhraeus **Board Member** 

- Member since 2015
- Founder of several international life science and technology companies, such as Cellavision AB, Precise Biometrics AB, and Anoto Group AB
- Currently Board member of Cellavision AB (publ), EQL Pharma AB (publ), Lund University innovation AB, the Tech Transfer Office at Lund University, and Reccan Diagnostics
- Chairman of FlatFrog Laboratories AB Lars Stigsson and Respiratorius AB (publ)
- · CEO of EQL Pharma AB (publ)



**Board Member** 

- Member since 2019
- MSc in Chemical Engineering (Lund University)
- Founder, among others, of SunPine AB and Sun Carbon AB. Co-founder of BioShare and TreeToTextile AB
- Inventor in over 20 patent series relating to biofuels, innovative textile fiber processes and forest industry biorefinery technologies
- Awarded with the Polhem Price in 2018



Anders Månsson **Board Member** 

- BSc in Business & Economics (Lund University), Executive MBA (Business School Lausanne, Switzerland).
- Member since 2015 with a break when he worked as Amniotics AB's CEO from Jun 2017 to May 2019.
- Previously at Meda Pharma (now Mylan), Ferring Pharmaceuticals, and LEO Pharma
- Former Member of the board of Respiratorius AB (Publ.): Industrial Advisor of Ratos AB, and Chairman of the Board of CanImGuide Therapeutics AB.
- Currently Member of the Board of EQL Pharma AB (publ) and CEO of RhoVac



- Co-founder. Member since 2015
- PhD (Lund University) CEO of the company during the first two years (2015- Jun 2017)

**Marcus Larsson Board Member** 

### New members and Chair



Peter Buhl Jensen Chairman

- To be elected at the AGM in 2021
- Founder of several international life science and technology companies. such as TopoTarget, Oncology Venture & Medical Prognosis Institute
- At TopoTarget Mr Buhl Jensen was instrumental in building a cutting edge pipeline via M&A of three companies and subsequent listing on the Copenhagen Stock Exchange
- On the board of directors at Symbion A/S. Cobis A/S and Wnt Research AB.



Ingrid Attervd Heiman **Board Member** 

- To be elected at the AGM in 2021
- Mrs Atteryd Heiman has previously worked as CEO for three successful companies, and held several board and chairman positions, with companies spanning the women's health, food, pharmaceutical, biotech, life science, and financial services.
- On the board of directors at Pharmiva AB Dignitana AB. Redwood Pharma AB. CarpoNovum AB
- Chariman of Doxa AB



**Christopher Bravery Board Member** 

- To be elected at the AGM in 2021
- Christopher Bravery is an experienced regulatory scientist with decades of experience from Pharma with primary focus on advanced therapies and regenerative medicine
- Mr. Bravery has deep understanding of EU clinical trials, EMA licensing and post-licensing requirements gained from time as an MHRA/EMA assessor



Fredrik Tiberg **Board Member** 

- To be elected at the AGM in 2021
- Fredrik Tiberg has since 2003 served as CEO of Camurus AB.
- Mr Tiberg has been instrumental in leading Camurus from being a promising research project to its current position as a fully-fledged Pharma company
- Mr Tiberg serves on the board of directors at Camurus Lipid Research Foundation



## **Key Value Drivers**

Targeting a fastgrowing billion dollar market

Patented technology and unique source of stem sells

Broad and diversified pipeline

Lucrative business model

**IPO** 

- Global Stem Cell Therapies represent a nascent but high potential market
- Forecasted to grow fast between 2019 2026, and reach \$3.1 billion in 2026
- Control of the full manufacturing process value chain, with global expansion potential
- Tissue-relevant neonatal MSC tailored for different diseases uniquely extracted from amniotic fluid
- Broad pipeline targeting attractive specialty disease markets
- Respiratory (Lung); Neurodegenerative (Brain); Nephrological (kidney);
   Dermatology (Skin)
- Flexibility to license to pharma companies at different stages of development, and manufacturing services
- Potential to create higher value in orphan drugs

IPO June 2021



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