Amniotics

Interim Report 3rd Quarter 2021

Preparing for clinical phase

July - September in brief

- Total revenues: SEK 0 (0) thousand.
- Operating profit (EBITDA): SEK -9,778 (-5,437) thousand.
- Result for the period: SEK -10,211 (-5,998) thousand.
- Earnings per share: SEK -0.64 (-0.54).
- Cash and cash equivalents at the end of the reporting period: SEK 54,158 (9,754) thousand.
- As a consequence of the exercise warrants series 2017/2021 and series 2018/2021, the share capital increased by 204,500 shares and the proceeds to the company amounts to SEK 1,842 thousand.
- Equity/assets ratio as per the end of the reporting period: 92 (88) %.
- Nasdaq Stockholm approved trading of Amniotics shares and warrants on Nasdaq First North Growth Market and the first day of trading was 6 July 2021.

January - September in brief

- Total revenues: SEK 0 (0) thousand.
- Operating profit (EBITDA): SEK -39,088 (-15,782) thousand.
- Result for the period: SEK -40,380 (-17,145) thousand.
- Earnings per share: SEK -2.55 (-1.54).
- Cash flow for the period: SEK 53,648 (3,727) thousand.
- In the second quarter Amniotics raised SEK 60 million for the Company before issue expenses in a rights issue.

Events after the end of the reporting period

- Lars Stigsson, a member of the Board of Directors of Amniotics AB (publ) resigned from the Board of Directors of the company on 12 October 2021.
- The members of the Nomination Committee were appointed and consists of: Christer Fåhraeus, Marcus Larsson, Lars Stigsson represented by Fredrik Tiberg and Peter Buhl Jensen, Chairman of the Board of Amniotics AB.

CEO Statement

Activity level was high in the third quarter, and we saw a continued growth in Amniotics organization and capabilities. With new members onboard, including external consultants, within the clinical and production area we have a trajectory set for continued focus on development and increasing the value of our programs.

During the quarter we have continued working on our pipeline. For our most advanced development project targeting ARDS/COVID-19, the core documents for the planned clinical trial in 2022 will soon be completed. We have advanced as expected and a number of clinical sites will be participating in the upcoming trial. The trial is thoroughly planned and will be finalized in collaboration with our Clinical Research Organization (CRO). We work closely with our CRO, and we are setting up the trial with risk mitigation strategies to keep pace with the development of the disease and to avoid any disruptions.

In addition to the advances in the planning of the study, we are currently manufacturing stem cells that will be used in humans in the ARDS/COVID-19 study. We have successfully completed a number of batches during the quarter and I'm happy to see that the quality, yield and manufacturing processes are in line with what we predicted. During the last quarter of the year, we will continue to manufacture batches of stem cells that will be used in the planned study in 2022.

Some of our peers within in the field of stem cells have shown effect with their investigative stem cell products. This despite COVID-19 being a disease which has experienced a changing treatment regimen during time and across continents. This makes it harder to show efficacy. With our peers results at hand, we have a strengthened belief in Amniotics PulmoStem product for this indication.

The ongoing COVID-19 pandemic is far from over. With new outbreaks and a virus that is mutating, there is currently a great need for an effective treatment for lung diseases related to this and the need will remain for a long time to come. FDA has created a special emergency program for possible coronavirus therapies, the Coronavirus Treatment Acceleration Program (CTAP) to move new treatments to patients as quickly as possible. Currently there are 660 drug development projects in planning stage.

"Continued progress executing on our strategy."

Along with the progress in trial planning for COVID19, Amniotics has also started to look into our two others respiratory indications and started to engage with clinical sites and clinicians.

Peers have shown potential effect in neurology indications. They produce MSCs with a different approach than the one Amniotics uses for CogniStem. We believe that CogniStem can deliver comparable or even stronger effects with its neonatal origin and neural specificity

In Amniotics ongoing pre-clinical program in pediatric neurology indication, we expect data outcome in Q4 this year and we expect to present this in 2022. As mentioned in our Q2 report earlier this year, Amniotics has strong pre-clinical data in lung transplantation, and we expect this data will be presented in 2022.

I am proud to mention that Amniotics was selected as a one of the "Rising Stars" by the Swedish American Life Science Society (SALSS) in mid-October.

I look forward to a continued eventful last quarter of 2021 and the preparation of the planned phase I study in ARDS/COVID-19 as the next important milestone.

Lund, November 2021

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.

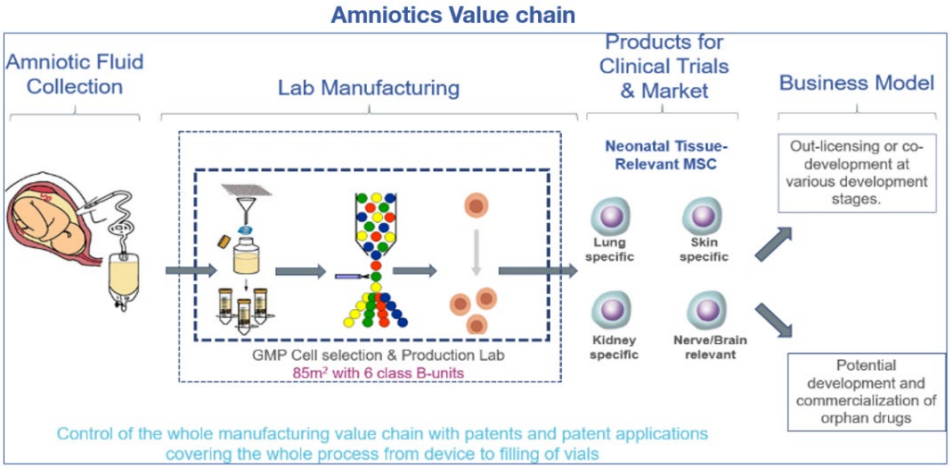
Amniotics is a biopharma company that develops cell therapy drugs based on mesenchymal stem cells (MSC) from amniotic fluid. These MSC are neonatal, which means that they are better than MSC from adult individuals in several important aspects (e.g., virus burden, growth capacity). As of now, it is Amniotics 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 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™). 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.

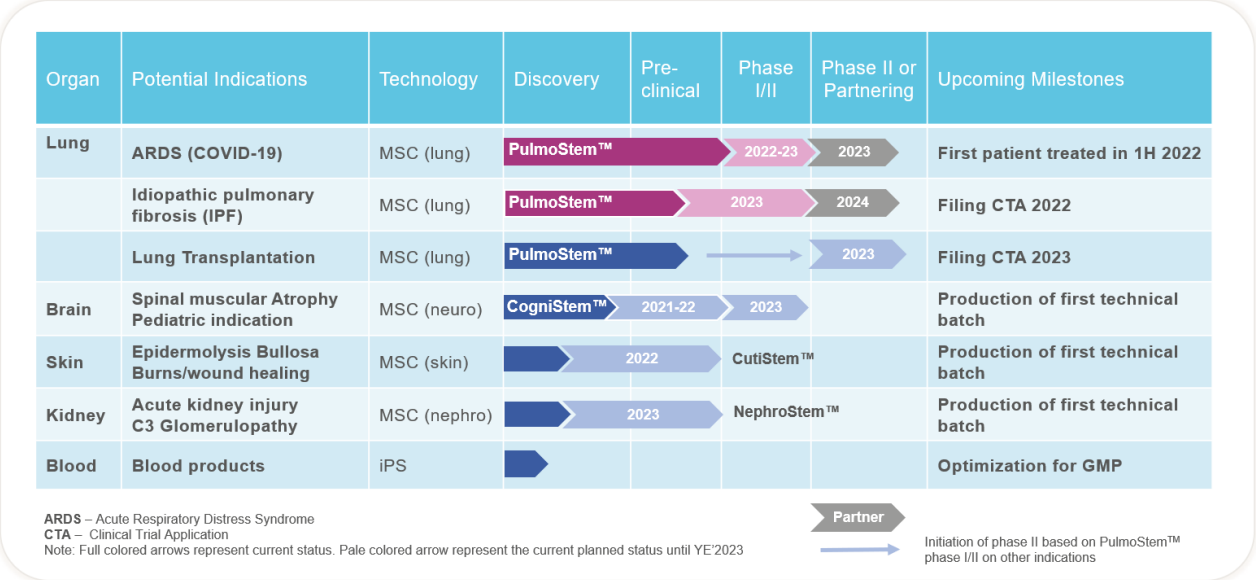
Amniotics has the capacity to work with other companies to add value through e.g.:

- 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

SEK 000	Q3 2021	Q3 2020	January - September 2021	January - September 2020	Full-Year 2020
Net sales	0	0	0	0	0
Operating result	-10,211	-5,997	-40,376	-17,142	-30,994
Cash flow from operating activities	43,661	-9,559	-6,044	-16,714	-61,772
Cash position	54,158	9,754	54,158	9,754	510
Equity/assets ratio %	92	88	92	88	79
Earnings per share (SEK)	-0.64	-0.54	-2.55	-1.54	-3,13

Financial overview

Comprehensive result
Comprehensive result for the third quarter was SEK -10,211 (-5,998) thousand, which corresponds to a decrease of SEK-4,213 thousand. Earnings per share, based on number of shares at end of the quarter, totaled SEK -0.64 (-0.54).

Comprehensive result for the period was SEK -40,380 (-17,145) thousand, which corresponds to a decrease of SEK -23,235 thousand. Earnings per share, based on number of shares at end of the period, totaled SEK -2.55 (-1.54).

Expenses
Operating expenses for the third quarter totaled SEK 9,778 (5,441) thousand, an increase of SEK 4,337 thousand. Expenses are allocated as follows: other external expenses SEK 6,190 (3,545) thousand, personnel costs increased by SEK 1,671 thousand due to increased number of employees and amounted to SEK 3,565 (1,894) thousand and other operating expenses SEK 23 (2) thousand.

Operating expenses for the period totaled SEK 39,116 (15,792) thousand, an increase of SEK 23,324 thousand. Other external expenses amounted to SEK 27,32 (10,499) thousand, an increase of SEK 16,822 thousand due to growing activities in the company´s lab driving costs for supplies/ materials SEK 835 thousand, clinical consulting costs increased approximately by SEK 6,688 thousand. Costs related to the listing on Nasdaq First North Growth Market in July and share issuing amounted to SEK 5,754 thousand. Personnel costs increased by SEK 6,372 thousand due to six additional headcounts compared to previous year and amounted to SEK 11,653 (5,281) thousand. Other operating expenses SEK 142 (12) thousand.

Investments
The company's net capital expenditure during the third quarter amounted to SEK 42 (357) thousand, including SEK 0 (249) attributable to property, plant, and equipment (mainly laboratory equipment), and SEK 42 (108) thousand relating to investments in intangible assets.

Capital expenditure for the period amounted to SEK 689 (3,355) thousand, including SEK 259 (3,166) thousand attributable to property, plant, and equipment (mainly laboratory equipment), and SEK 429 (239) thousand relating to investments in intangible assets.

Cash flow and financial position
Total shareholders' equity at end of the period was SEK 62,768 (19,560) thousand 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 3.91 (1.75). The company's equity ratio at the end of the quarter was 92 (88) percent.

Cash and cash equivalents at the end of the period amounted to SEK 54,158 (9,754) thousand. The money from the rights issue in June, SEK 60 million, was paid into the company's account in July.

Cash flow for the quarter was SEK 45,261 (9,244) thousand. Cash flow from financing activities totaled SEK 58,921 (4,636) thousand.

Cash flow for the period was SEK 53,648 (3,727) thousand. Cash flow from financing activities during the period totaled SEK 60,381 (23,796) thousand.

Organization
The number of employees at the end of the reporting period was 15, an increase of 6 people compared with the same period last year when the company had 9 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. As a consequence of the exercise warrants, series 2017/2021 and series 2018/2021 during the quarter, the share capital increased by 204,500 shares and the proceeds to the company amounts to SEK 1,842 thousand.

Other information

Risks factors
A pharmaceutical development company such as Amniotics is exposed to significant operational and financial risk. 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.

Effects of the covid-19 pandemic
The covid-19 pandemic is impacting, and will continue to impact, all aspects of society for a very long time to come. The immediate effects on Amniotics' operations are so far limited. With the majority of the development projects proceeding according to plan, Amniotics is positioned to make additional advances. Amniotics employees continues work as usual but are making use of digital technology to minimize the number of social contacts. Amniotics' monitors continuously the development of the covid-19 pandemic and its consequences for the company.

Auditor's review
This report has not been reviewed by the Company's auditor.

Liquidity and financing
The board and company management are assessing alternatives to secure the company's long-term capital requirement on an ongoing basis.

The share
The number of shares at the end of the period amount to 16,033,330. All shares are of the same class and have the same voting right. Amniotics shares are traded on Nasdaq First North Growth Market and traded under the ticker symbol AMNI and ISIN code E0015961016. First North is Nasdaq's European emerging market intended for small, growing businesses, with a less extensive rulebook than the main market.

Legal disclaimer
This report contains forward-looking statements that constitute subjective estimates and forecasts about the future. Assessments about the future are only valid on the date they are made and are, by their nature, similar to research and development work in the biotech field, associated with risk and uncertainty. In light of this, actual outcomes may differ substantially from what is described in this report.

Future reporting dates

- Year-end Report 2021, Feb 17th, 2022.
- Q1 Interim report 2022, May 10th 2022
- Annual General Meeting 2022, May 19th 2022
- Q2 Interim report 2022, Aug 16th 2022
- Q3 Interim report 2022, Nov 10th 2022
- Year-end Report 2022, Feb 16th 2023

The financial reports will be made available on the Amniotics website:
https://www.amniotics.com/investors/financial-reports/

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Certification by the Board of Directors and Chief Executive Officer

The Board of Directors and the Chief Executive Officer certify that this interim report provides a true and fair overview of the development of the Company's business activities, financial position and results of operations and describes significant risks and uncertainties facing the Company.

Lund, November 12, 2021

Amniotics AB (publ)

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

Financial Statements

Income statement in Summary

SEK 000	Q3 2021	Q3 2020	Jan - Sep 2021	Jan - Sep 2020	Full-Year 2020
Net sales	0	0	0	0	0
Other operating income	0	4	28	10	38
Operating income	**0**	**4**	**28**	**10**	**38**
Operating expenses					
Other external costs	-6,190	-3 545	-27,321	-10 499	-21,586
Personnel costs	-3,565	-1 894	-11,653	-5 281	-7,842
Other operating costs	-23	-2	-142	-12	-18
Operating result before depreciation and amortization (EBITDA)	**-9,778**	**-5 437**	**-39,088**	**-15 782**	**-29,408**
Depreciation of tangible and intangible assets	-433	-560	-1,288	-1 360	-1,586
Operating result (EBIT)	**-10,211**	**-5 997**	**-40,376**	**-17 142**	**-30,994**
Net financial items	0	-1	-4	-3	-3
Result after financial items	**-10,211**	**-5 998**	**-40,380**	**-17 145**	**-30,997**
Taxes	0	0	0	0	0
Result for the period	**-10,211**	**-5 998**	**-40,380**	**-17 145**	**-30,997**

	Q3 2021	Q3 2020	Jan - Sep 2021	Jan - Sep 2020	Full-Year 2020
Earnings per share (SEK)*	-0.64	-0.54	-2,55	-1.54	-3.13
Number of shares**					
Weighted average for the period	16,014,982	9,898,918	13,779,751	9,462,306	9,891,856
Number of shares at start of period	15,861,830	9,244,000	11,166,500	9,244,000	9,244,000
Number of shares at end of period	16,066,033	11,166,500	16,066,033	11,166,500	11,166,500

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

*** In Q2 2021 the company's shares were split in the ratio 500: 1.*

Balance sheet in Summary

SEK 000	Sep 2021	Sep 2020	Dec 2020
Assets			
Subscribed but not paid share capital	0	0	37,846
Fixed assets			
Intangible assets	4,181	3,565	3,752
Equipment and installations	8,345	7,676	9,374
Total fixed assets	12,526	11,241	13,125
Current assets			
Other receivables	1,237	1,156	1,970
Cash and bank balances	54,158	9,754	510
Total current assets	55,395	10,910	2,480
Total assets	**67,921**	**22,151**	**53,451**
Shareholders' Equity and Liabilities			
Shareholders' equity			
Restricted equity			
Share capital	869	604	604
Not registered share capital	0		96
Reserve for development expenses	167	29	167
Non- restricted equity			
Share premium reserve	60,793	55,789	90,549
Accumulated loss including profit/loss for the period	939	-36,862	-49,229
Total shareholders' equity	62,768	19,560	42,186
Liabilities			
Liabilities to credit institutions, long-term	600	0	599
Current liabilities	4,553	2,591	10,666
Total liabilities	5,153	6,727	11,265
Total shareholders' equity and liabilities	**67,921**	**22,151**	**53,451**

Financial key ratios

Shareholders' equity per share, SEK	3.907	1.217	3.778
Equity/assets ratio %	92	88	79

Changes in equity

SEK 000	Jan - Sep 2021	Jan - Sep 2020	Full Year 2020
Opening balance	42,186	12,909	12,909
Issue of shares	60,962	23,796	60,275
Loss for the period	-40,380	-17,145	-30,997
Equity at end of period	**62,768**	**19,560**	**42,186**

Cash Flow statement

SEK 000	Q3 2021	Q3 2020	Jan - Sep 2021	Jan - Sep 2020	Full-Year 2020
Operating result	-10,210	-5,997	-40,376	-17,142	-30,994
Amortization and depreciation	433	561	1,288	1,360	1,586
Other, including non-cash items	-22	63	-89	61	61
Cash flow from operating activities before change in working capital	**-9,799**	**-5,374**	**-39,177**	**-15,721**	**-29,347**
Change in working capital	53,460	-4,185	33,133	-993	-32,425
Cash flow from operating activities	**43,661**	**-9,559**	**-6,044**	**-16,714**	**-61,772**
Investing activities	-42	-357	-689	-3,355	-5,466
Cash flow after investing activities	**43,616**	**-9,916**	**-6,733**	**-20,069**	**-67,238**
Financing activities	-200	0	-582	0	1,446
Rights issue	1,842	19,160	60,963	23,796	60,275
Change in cash and cash equivalents	**45,261**	**9,244**	**53,648**	**3,727**	**-5,517**
Cash and cash equivalents at the beginning of the period	8,897	510	510	6,027	6,027
Cash and cash equivalents at the end of the period	**54,158**	**9,754**	**54,158**	**9,754**	**510**

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.

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