Year-End Report for the cell therapy company

NextCell Pharma AB

September 2020 – August 2021

cellaviva

Cellaviva™ NextCell's stem cell bank, which offers family saving of stem cells for possible future medical needs - now the largest in Scandinavia.

nextcell pharma

ProTrans™ NextCell's proprietary cell product for the treatment of autoimmune and inflammatory diseases. Significant effect shown in diabetes.

NextCell Pharma AB (publ.) | 556965-8361 | nextcellpharma.com | cellaviva.se

Content

01.

Year-End Report

"NextCell", “NXTCL” or "Company" refers to NextCell Pharma AB, organization number 556965-8361. The amount in brackets refers to the corresponding period in the previous year. Note that the Company's fiscal year is September 1-August 31. This English version is a translation of the Swedish version. The Swedish version is at all times to be seen as the leading document.

Fourth quarter (2021-06-01 until 2021-08-31)

- Operating income amounted to TSEK 1 381 (842).
- Operating result amounted to TSEK -4 475 (-4 877).
- Earnings per share* amounted to SEK -0,13 (-0,22).
- Cash and bank amounted to TSEK 139 168 (21 958).
- Solidity** amounted to 96,4 (88,1) %.

Twelve months (2020-09-01 until 2021-08-31)

- Operating income amounted to TSEK 4 455 (4 166).
- Operating result amounted to TSEK -24 557 (-17 681).
- Earnings per share* amounted to TSEK -0,81 (-0,89).

**Result per share: operating results divided by the average number of shares. Average number of shares for the fourth quarter of 2020/2021 is: 34 379 523 (22 011 081) shares and the average number of shares for the twelve month period is: 30 411 847 (19 864 756). Number of shares in NextCell as per August 31st 2021 is: 34 379 523 (23 398 334).*
***Solidity/Equity ratio: shareholders' equity of the balance sheet total.*

Significant events during the fourth quarter of 2020/2021

- NextCell announced in the beginning of June that the first patient with severe pneumonia, as a result of COVID-19 infection, had been treated with ProTrans. The patient was hospitalized at Örebro University Hospital, where the phase Ib study ProTrans19+SE is in progress led by Principal Investigator Associate Professor Josefin Sundh.

- In the middle of June NextCell announced that a scientific advisory meeting with the European Medicines Agency (EMA) had been held regarding ProTrans and the path forward to a possible market approval. The focus was the design of the phase III study ProTrans-3.

- NextCell announced in the end June a joint venture together with their long-term collaborator and contract manufacture organisation, Polski Bank Komórek Macierzystych (PBKM, FamiCord Group). NextCell acquired ~10 % of shares in the newly started company FamiCordTx through a directed equity issue, raising the capital with 0,5 MEuro in cash. FamiCordTx has exclusively licensed a patent pending CAR-T technology and the tech transfer has been completed, and the production of CAR-T cell therapy was awaiting ATMP manufacturing approval before production of CAR-T for clinical trial use could be started.

- In the middle of August NextCell announced that a patent application had been filed for the treatment of Sars-CoV-2 mediated severe pneumonia with ProTrans. NextCell increased the IP protection for the drug candidate ProTrans for the treatment of autoimmune diseases and inflammatory conditions.

- NextCell announced in the end of August that Patrik Fagerholm had been appointed as interim CFO, replacing Sofia Fredriksson.

Significant events after the reporting period

- NextCell announced in the beginning of September that three patients with Covid-19 had been treated with ProTrans in the Swedish study ProTrans19+SE conducted at Örebro University Hospital. As a result, all patients in the low-dose cohort had at point been treated.

- In the beginning of October NextCell announced that their CEO, Dr. Mathias Svahn, was presenting clinical data from the ProTrans-1 and ProTrans-2 diabetes studies.

- NextCell announced in the end of October an updated strategy for ProTrans clinical trial program in Type 1 diabetes that will increase the Company’s market potential and reduces its risk.

- NextCell Pharma AB announced in the end of October that the clinical trial ProTrans19+SE can commence to enroll patients in the medium dose group. Three patients having recieved a low dose ProTrans, have been clinically assessed and evaluated by the Data and Safety Monitoring Board, which allows continuation with medium dose treatment ProTrans for COVID-19 induced ser pneumonia.

02.

NextCell Pharma

- next generation cell therapy

NextCell's drug candidate ProTrans represents a platform technology to develop and manufacture cell therapies to treat autoimmune diseases and inflammatory conditions. The company has come the furthest with ProTrans for the treatment of type 1 diabetes where both safety and efficacy in preserving patients' ability to produce their own insulin have been demonstrated in clinical trials.

NextCell was founded in 2014 by researchers at Karolinska Institutet, under the name Cellaviva AB. Today, the Company has two business areas, in addition to ProTrans and the Company's patent pending selection algorithm, NextCell also controls the stem cell bank Cellaviva, This is Sweden's first and the largest stem cell bank in the Nordic region for family saving of stem cells. Cellaviva offers parents to collect and store their newborn baby's stem cells, derived from umbilical cords, for the future medical needs of their child and family. Cellaviva is the only stem cell bank in Sweden with permission from the Swedish Health and Social Care Inspectorate (IVO).

03.

CEO Comments

At the beginning of our fiscal year, September 2020, we presented positive results from ProTrans-2. The phase II study demonstrated that patients treated with a single infusion of ProTrans maintained a statistically significantly higher ability to produce endogenous insulin after one year compared to patients treated with placebo and the study achieved its primary efficacy endpoint.

Furthermore, results from the follow-up study, ProTrans-Repeat, were published in December 2020. In addition to the primary purpose being safety, a clear tendency towards sustained efficacy over two years was observed in respect to maintaining insulin production in patients receiving a second high dose infusion of ProTrans.

It is a statement of strength to be able to demonstrate statistically significant efficacy with so few patients. There are substantial individual differences in the course of the disease in patients newly diagnosed with type 1 diabetes and a treatment effect is at risk of being blurred due to natural variation. This has not been the case for ProTrans.

It has been a deliberately risky strategy to drive the development of ProTrans with small studies that treat a limited patient group. We have justified the risk with our data-driven selection algorithm to identify potent cells that produce efficacious ProTrans. Small studies can be enforced quickly and with modest resources. NextCell has during the year had a constructive dialogue with the European Medicines Agency (EMA) on the path to commercialization. We see good opportunities to obtain permission to conduct a phase III study that can be the basis for marketing approval.

We executed our largest preferential rights issue of SEK 150 million in December. A few months later, together with Professor Per-Ola Carlsson and Uppsala University, we were able to present the approval of a clinical trial in children and adolescents. ProTrans-Young is a tremendously important study in which a total of 66 children and adolescents with type 1 diabetes will be treated with ProTrans or placebo. A significant number of patients in an patient group with high unmet medical need that NextCell has not been able to include in the safety-oriented first part of the trial program. The study is investigator-initiated and paid for with research grants, NextCell contributes with study drugs.

Type 1 diabetes is usually diagnosed at the age of 10-14 years. Patients with onset of diabetes early suffer more complications later in life and have a reduced life expectancy. Younger patients have the greatest medical need, and we have scientific rationale for why younger people treated early may also respond better to treatment.

ProTrans-OBS and Protrans-Repeat are continuation studies on ProTrans-1 and ProTrans-2 where patients are followed for a longer period of time, after either one or two treatments. By the end of 2021, we will have 3 years of data on repeated treatment and by mid-2022 also 3 years follow-up of patients who have received a single dose. Long-term efficacy and safety provide additional support for a phase 3 application and data can also lead to minor adjustments in study design, for example having annual treatments.

At the end of October (after the end of the period) we communicated an updated strategy for ProTrans's clinical trial program. The aim is to increase potential while reducing the risk. We can achieve this by waiting for preliminary safety data from the approved ProTrans-Young pediatric trial before submitting the application for ProTrans-3, scheduled for H2 2022.

The pandemic has had a marginal impact on NextCell's drug development. Deliveries of consumables and equipment have sometimes been delayed, but the clinical trials have not been affected. During the spring, a European prefeasibility was conducted, i.e. we investigated whether hospitals across Europe are interested in participating in a study. There was a lot of interest, but hospitals in some countries stated that they could only prioritize basic medical care. Heavily affected countries such as Italy has an extremely strained healthcare system. The situation probably improves over time and the study team naturally takes the pandemic into account in the selection process of participating hospitals.

Our clinical trials in COVID-19 are ongoing.At the time of writing, we have just received notification from the Data Safety and Monitoring Board that they allow us to proceed with treatment of patients in the medium dose group. The number of cases have been fluctuating over time and been low in Canada, but are now raising.

A restraining order at Swedish hospitals during the pandemic has led to challenges for Cellaviva's collection staff. Instead of being able to do the stem cell collection in the delivery room, we have used "Cellbulances", ambulating stem cell laboratory that looks like ambulances. The cellbulance is parked outside the entrance to the maternity clinic and immediately after the birth, the afterbirth is handed out to the phlebotomist in the cellbulansen who do the stem cell collection in the car's laboratory.

NextCell has now completed the shell of its own GMP facility for the production of ProTrans. The GMP facility is expected to be ready for production of ProTrans in 2023. Own manufacturing is an important step for partnering and licensing discussions.

ProTrans is an immunomodulatory drug candidate with the potential to be active for a range of autoimmune diseases and inflammatory conditions. The patent pending selection algorithm, which is used to define ProTrans and ensure effective treatment, can be fine-tuned to match specific diseases. The platform technology is intended for the treatment of applications as diverse as chronic autoimmune diseases and acute hyperinflammation induced by viruses.

NextCell is maturing and we believe we have proven that ProTrans is effective. The company is now participating in studies covering both diabetes and Covid-19. We bring the technology home to our own production facility, and work to continue to create value for patients and for our shareholders.

Huddinge, October 2021
Mathias Svahn, CEO

04.

Portfolio

NextCell's product portfolio is based on mesenchymal stroma cells (also called stem cells) from Wharton's Jelly (WJMSCs), that is, the gel found around the blood vessels in the umbilical cord tissue. Mesenchymal stroma cells have an immunomodulatory ability, an attribute useful in a variety of areas where there is currently great potential for improvement, such as the treatment of autoimmune diseases and inflammatory conditions.

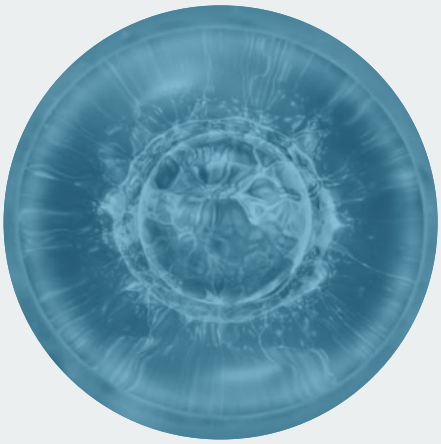
Currently, there are a number of approved treatments with mesenchymal stroma cells from, for example, fat and bone tissue, but no established treatment method with mesenchymal stroma cells from umbilical cord tissue. However, many clinical trials involving stroma cells from umbilical cord tissue are ongoing globally.

The foundation of NextCell's cell therapies is the Company's proprietary selection algorithm, which consists of a patent-pending method for selecting the most potent cells. The algorithm makes an overall assessment of several functional analyses to identify optimal donors and cells for the manufacture of cell therapy, ProTrans. Only the cells that demonstrate the desired immunomodulatory effect are selected.

NextCell's precise and advanced selection method allows scalability where the cells have high potential strength and effect for a particular application compared to non-specially selected cells. The selection method results in cells of consistently high quality with a good safety profile and with few side effects. **The selection algorithm is currently protected by three pending patent families.**

Furthermore, NextCell's competitiveness lies in the use of progenitor cells from the umbilical cord. A tissue containing potent and naive cells with the possibility of rapid expansion. NextCell's cell therapy products are allogeneic, which means that donated cells are used, without having to match donors and recipients.

05.



ProTrans™

ProTrans™ (ProTrans) is the Company's first drug candidate, based on the selection algorithm and developed for the treatment of type 1 diabetes. Type 1 diabetes is an autoimmune disease in which the body's immune system attacks the insulin-producing beta cells in the pancreas. The causes of this autoimmune reaction are not fully known and are not linked to lifestyle factors.

There is currently no cure for diabetes and the disease cannot be prevented. Approximately 5–10 percent of patients with diabetes have type 1 diabetes, which usually debuts in children and young adults. Approximately the same number have an adult form of autoimmune diabetes, LADA (Latent Autoimmune Diabetes in the Adult) and globally around 80 million people live with some form of autoimmune diabetes.

ProTrans is made from cells derived from donated umbilical cords. The umbilical cord is a rich source of stem cells that can be recovered at birth and cryopreserved for a long time. The willingness to donate is high for umbilical cord tissue because the collection is completely risk-free and the tissue is redundant. ProTrans is produced by contract manufacturing organizations (CMO) according to NextCell's criteria. NextCell's ultimate goal for ProTrans is to be able to treat people at risk of developing type 1 diabetes even before they become dependent on external insulin (prevention). By treating with ProTrans, the immune system is taught not to attack the insulin-producing beta cells, which can result in an extended period without external insulin need and thus a longer period without complications.

As safety and immunomodulatory effect have been demonstrated in phase I and phase II clinical trials, treating diabetes. ProTrans may also be effective for other types of inflammatory and autoimmune diseases. NextCell is conducting, in parallel with the clinical trial program for type 1 diabetes, studies in which Covid-19 patients are treated with ProTrans. The later serious stage of Covid-19 is caused by the immune system becoming hyperactive and attacking various organs, including the lungs. The hypothesis is that by treating patients before they reach this life-threatening condition, severe disease can be prevented.

ProTrans™ – carefully selected cells

The drug candidate ProTrans™ is a cell therapy product with cells from umbilical cord tissue. The cells are carefully selected using NextCell's patent pending selection algorithm.

In the cleanroom laboratory, a variety of analyses are carried out to evaluate the function of the cells and how they affect the immune system. The results are entered into the selection algorithm that calculates the cells' combined ability to suppress an overactive immune system via multiple mechanisms of action.

ProTrans™ – biological intelligence

The immune system consists of a variety of cell types that are activated or inactivated by a large number of different signaling molecules. In autoimmune diseases, the balance has been disrupted and the immune system is attacking after the body's own cells. The molecular cause is usually unknown and varies between individuals and can change over time.

ProTrans™ utilizes the body's own way to restore balance. The mesenchymal stromal cells can sense the molecular cause of autoimmunity and secrete signaling molecules to counteract inflammation.

ProTrans™ – industrially designed cell therapy

NextCell has developed ProTrans™ with the aim to set on the market. Mesenchymal stroma cells from umbilical cord can be grown in large quantities and the availability of raw materials is almost unlimited.

Treatment with ProTrans™ is simple and safe and would be possible to administer at smaller hospitals. ProTrans™ is delivered frozen in a small cell bag. After 3 minutes, the ProTrans™ is thawed and the cell bag is connected to a regular infusion bag. The cells are gently mixed with a saline solution before being given as an infusion into a blood vessel in the elbow.

06.

Clinical trials with ProTrans™

ProTrans-1

ProTrans-1 was started in January 2018, a phase I study evaluating ProTrans's safety and impact on the patient's own insulin production. The study treated a total of nine patients with low, medium and high dose. Results from the study were reported in December 2019 and showed, in addition to proven safety, a statistically significant difference in own insulin production between the different patient groups. Patients in the high- and medium-dose had maintained a higher insulin production compared to patients in the low-dose cohort.

ProTrans-2

ProTrans-2 was a randomized, double-blinded and placebo-controlled phase II study with efficacy as the primary endpoint. Ten patients were treated with ProTrans and five patients were treated with placebo. The last patient in ProTrans-2 was treated in June 2019 and results were published in September 2020. The fact that the study was double-blind ensured that neither patients nor doctors knew whether they had received active treatment or placebo during the 12-month follow-up period. The results showed that patients treated with a dose of ProTrans had maintained a statistically significantly higher insulin production after a 12-month period compared to patients treated with placebo.

ProTrans-Young

ProTrans-Young is an academic trial (Investigator initiated) run by Uppsala University in collaboration with Linköping University and Lund University. The purpose, as the name suggests, is to evaluate ProTrans for the treatment of young patients with type 1 diabetes. The first part of the study focuses on safety of treating adolescents aged 12-18 years in the same manner as adults have been treated. After that, the age the patients is further declined to treat children from 7-11 years of age.

The primary endpoint of second part of ProTrans-Young is efficacy in adolescents, 30 patients 12-18 years and then 30 patients 7-11 years. Patients are randomized to placebo or ProTrans (1:1).

The study is approved and the first patient is expected to be included in Q4 2021. Uppsala University is the sponsor of the study, which is paid for with research grants. NextCell contributes ProTrans. The principal investigator is Professor Per-Ola Carlsson and co-investigators are Professor Helena Elding Larsson, Skåne University Hospital and Professor Johnny Ludvigsson, Linköping University Hospital. ProTrans Young is a phase I/II study enrolling a total of 66 patients.

ProTrans-3

ProTrans-3 is the planned Phase III study that will form the basis for the application for marketing approval of ProTrans for the treatment of type 1 diabetes. The ProTrans-Young study will be able to provide early safety data for adolescents and children, opening up to include patients under the age of 18 in a pivotal trial.

A phase III study represents a significant investment for the company, it is therefore justified to wait for preliminary safety data from ProTrans-Young to double the addressable patient population. The application for permission for ProTrans-3 is planned for H2 2022.

ProTrans-Repeat

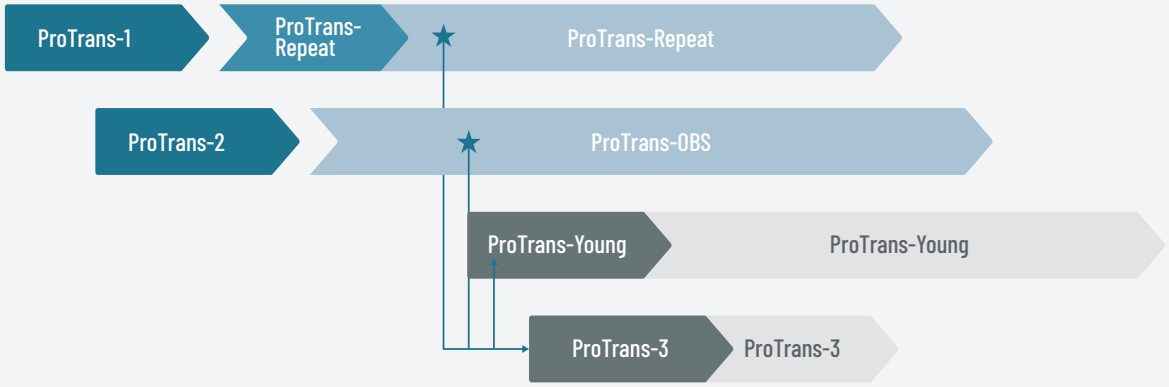
ProTrans-Repeat was started in May 2019 and is a continuation study of ProTrans-1 with the aim to collect data on repeated treatment, i.e. evaluating whether repeated treatment can increase or maintain the effect of ProTrans over a longer period of time while maintaining safety. The study includes the nine patients treated in ProTrans-1 and another six who act as a control group. Efficacy is measured by comparing the patient's ability to produce insulin before treatment and 12 months after treatment with a repeated dose of ProTrans. The last patient in ProTrans-Repeat was treated in September 2019 and data were published in December 2020. The results show safety, no serious adverse reactions were recorded during the 12-month follow-up period after the second dose of ProTrans. Furthermore, a clear tendency towards persistent efficacy was observed while maintaining insulin production in the three patients receiving a high dose of ProTrans.

The study follows patients for a total of 5 years and in Q4 2021, 2 years of visits to ProTrans-Repeat are carried out, which also means more than at least 3 years since the first treatment in ProTrans-1. Long-term data is valuable and gives NextCell a big head start over competitors.

ProTrans OBS

The observational study, ProTrans-OBS, was approved by the Ethical Review Authority in December 2020. The study is a follow-up to the ProTrans-2 clinical trial in which patients who completed ProTrans-2 are asked to participate for semi-annual follow-up of safety and efficacy over a period of four years. ProTrans-OBS is conducted by Professor Per-Ola Carlsson at Uppsala University and is a non-intervention study, i.e. the included patients will not be given any further experimental treatment with ProTrans, only clinically assessed during the followed up time. As stated above, ProTrans-Repeat was able to demonstrate both sustained efficacy and safety over a two-year period where an additional high dose of ProTrans was given after 12 months. The long-term efficacy of single infusion compared to two infusions is evaluated by running the two ProTrans-Repeat and ProTrans-OBS studies in parallel.

Figure: Overview of the diabetes clinical trial program. Ongoing clinical trials will contribute and strengthen the application for ProTrans-3 and future application for marketing authorization.



ProTrans-Repeat will contribute with 3 year data of patients treated with two infusions, in total 9 patients (3 low, 3 medium and 3 high dose).

ProTrans-OBS will contribute with 3 year efficacy and safety data in randomized placebo controlled patients, in total 9 patients treated with ProTrans and 5 placebo.

ProTrans-Young part 1 will contribute with safety data for treatment of children with ProTrans. 3 patients 12-18 years and 3 patients 7-11 years old.

ProTrans-Young part 2 will probably have started with preliminary safety data from ProTrans infusion in pediatric patients. Ongoing treatment of 12-22 years and 7-11 years. Total 60 patients randomized 1:1

ProTrans for the treatment of Covid-19 and other respiratory diseases

ProTrans is an immunomodulatory cell therapy and in addition to type 1 diabetes, it is assumed to be effective in several other auto-immune diseases and inflammatory conditions. The severe stage of Covid-19 is caused by the immune system becoming hyperactive and attacking organs, including the lungs. The hypothesis is to treat patients with ProTrans before they reach this life-threatening condition.

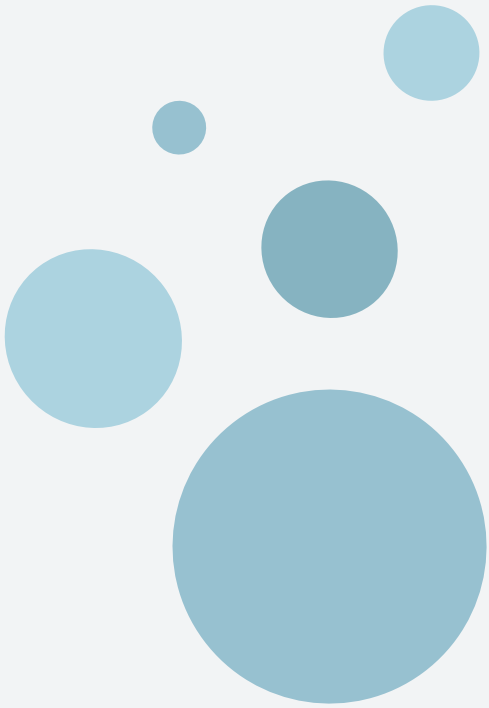
Currently, two clinical trials are conducted in which COVID-19 patients are treated with the drug candidate ProTrans.

ProTrans19+SE

In mid-May 2021, after receiving approval from both the Ethical Review Authority and the Medical Products Agency, ProTrans19+SE was started, where COVID-19 patients are treated with the drug candidate ProTrans. In this open-label Phase Ib study, a total of three groups of three patients will be treated with different doses of ProTrans. The study is conducted at The University Hospital in Örebro in collaboration with the Division of Clinical Trials and Karolinska Trial Alliance.

ProTrans19+CA

McGill University in Montreal has been granted permission by Health Canada to conduct a Phase II study with ProTrans to treat hyperinflammation in the lung caused by the coronavirus. Sponsors of the study are the Research Institute of the McGill University Health Centre and NextCell contributes study drugs. The study includes 48 patients with severe pneumonia and confirmed Covid-19 where equal parts are randomized to ProTrans treatment (24 patients) and placebo (24 patients).



Company history

2014
The company was founded by scientists at Karolinska Institutet, Dr Mathias Svahn, CEO, and Professor Edvard Smith, CMO.

2015
First offering stem cell banking of cord blood and tissue derived stem cells.

2016
First batch of ProTrans produced according to GMP.

2017
Approval of first clinical trial with ProTrans, 2017ProTrans-1.

2018
ProTrans-1 was shown safe in all three evaluated doses.

2019
All patients in both ProTrans-1 and ProTrans-Repeat have been treated.

2020
Positive data with statistical significance is published for ProTrans-2.

2021
Clinical trials for the treatment of COVID-19 with ProTrans are started.

Note: To simplify for the reader, the short name of the study titles has been changed. Formally, ProTrans-1 and ProTrans-2 are a single phase I/II study with EudraCT No: 2017-002766-50. ProTrans-Repeat can be seen as a continuation study of ProTrans-1 where patients in the dose escalation part have undergone an additional treatment with ProTrans, EudraCT No: 2018-004158-11.

07.

Employees

Sofie Falk Jansson is driven by simplifying the complex and highlighting an opportunity that pregnant parents only have once in lifetime.

Three years ago, Sofie Falk Jansson, Commercial Director at Cellaviva, chose to switch industry from business-to-business (B2B) sales to a key role at an expansive stem cell company. She uses her solid experience in sales and marketing to drive Cellaviva's growth forward and to reach out to more parents-to-be with the message of stem cell potential. For Sofie Falk Jansson, it makes sense that what she works with on a daily basis can help save lives in the future.

Stem cells from umbilical cord blood are already used as standard treatment for over 80 life-threatening diseases. Research suggests that umbilical cord stem cells in particular will revolutionise the treatment of degenerative diseases in the future.

"I caught the eye of Cellaviva during parental leave with my second child. I came into contact with a person who worked at the company and who told me about the possibility of saving umbilical cord stem cells at birth. I immediately found it extremely interesting but at the same time felt a frustration that I did not know and been able to seize this opportunity when my own children were born," says Sofie Falk Jansson.

The person she came into contact with would leave the company and eventually Sofie was offered her position as Head of Sales and Marketing.

"I felt that this was a role where I could really benefit by creating a broader general knowledge about stem cell saving. I am responsible for the commercial strategy of the biobank business and I am driving the action plan for Cellaviva's growth. I am also responsible for our network of healthcare professionals who carry out stem cell collections in Scandinavia," says Sofie Falk Jansson.

Interest in stem cell saving is gradually increasing

"It was an interesting challenge for me, who has worked fifteen years with sales and marketing within B2B, to change direction and instead apply to a Life Science company. We market not only a product, a stem cell saving, but for many of our customers it is more about the security of being able to offer their family future treatment options," says Sofie Falk Jansson.

An important part of her work is to inform prospective parents about how stem cell saving works and why it is a long-term good investment in the future health of the family.

"In my three years at Cellaviva, an enormous amount has happened. Our network of umbilical cord stem cell collectors has grown exponentially throughout the Nordic region, in order to meet demand. Interest in saving cells is increasing year by year. Stem cell saving is relatively complex, my task is to simplify and explain it in a way that allows as many people as possible to both understand what it means and realize why you should invest in it," says Sofie Falk Jansson.

"My original goal, to increase parents-to-be's awareness of the possibility of saving umbilical cord stem cells and thereby being able to treat degenerative diseases in the future, lives on. More than 120,000 children are born annually in Sweden alone, so the growth potential is extensive," says Sofie Falk Jansson.

08.

Cellaviva – from birth to life

NextCell operates, in addition to the development of stem cell therapies for autoimmune and inflammatory diseases and conditions, Sweden's first and the largest biobank for stem cells in the Nordic region, Cellaviva. Cellaviva offers pregnant parents the opportunity to collect and save stem cells from postpartum delivery. They consist of haematopoietic (blood-forming) stem cells from umbilical cord blood and mesenchymal stem cells (forming bones, cartilage, muscles and fat, among others, and are immunomodulatory) from the umbilical cord tissue.

Cellaviva has grown to become the largest biobank in Scandinavia and the only stem cell bank with permission from the Swedish Inspectorate for Health and Social Care (IVO). After the expansion to Denmark and with a staff of collectors across much of Scandinavia, demand is continuously increasing.

Cellaviva launched its product in September 2015 and the market potential in Sweden can still be considered incredibly large today. Abroad, stem cell savings have been around for decades and are globally an established and widespread service. The penetration of the stem cell saving market is thus very different from country to country. Singapore is the highest at over 20%, while European countries are usually below 5%. The company estimates that Scandinavia is far behind and that awareness that there are stem cells in the afterbirth is low.

Umbilical cord blood stem cells have been used in healthcare and research for over 30 years. Previously, bone marrow was the only stem cell source. In comparison to bone marrow stem cells, stem cells in umbilical cord blood are more immature and have a greater adaptability. This means that umbilical cord blood is less prone to cause complications during transplantation. The immature of the cells is a great advantage, as they are more adaptable to the tissue type and it is easier to match transplant patients with umbilical cord blood than with other stem cells. Tissue matching does not have to be as consistent as for bone marrow.

Extensive research is conducted with stem cells. Currently, more than 2,500** clinical trials are underway globally with experimental therapies for diseases such as cancer, diabetes, CP damage. Alzheimer's, MS, ALS and more. The goal is to develop new ways to treat today's incurable diseases

The company believes that stem cell research, given its scope, will bring major changes for future disease treatments.

Stem cells are currently used to treat a variety of serious diseases, such as congenital blood and immunodeficiency diseases, blood cancer, bone marrow diseases and hereditary metabolic diseases. By saving the newborn baby's stem cells, severe diseases can be treated and waiting times shortened in a critical course of disease as matching stem cells are already available. Even family members can, if match exists, be treated with the saved stem cells of the newborn baby.

Read more about family saving stem cells on https://cellaviva.se/

* *www.clinicaltrials.go*

09.

Development in numbers during the period

CFO Patrik Fagerholm comments on financial developments

Amounts in brackets refer to the corresponding period of the previous year.

Turnover

Operating income for the fourth quarter 2020/2021 amounts to SEK 1.4 (0.8) million, of which SEK 1.2 (0.8) million relates to revenue from Cellaviva's operations, which means that revenues have increased slightly between periods. Revenues related to Cellaviva have shown steady growth over the past two financial years, albeit with a slowdown at the beginning of the financial year, which can be explained in its entirety by the current pandemic. The restrictions on birth bans on Cellaviva staff have made some of the planned stem cell collections impossible. Furthermore, we see that the economic crisis caused by the pandemic leads to potential customers refraining from investing in stem cell savings. Fortunately, however, we can see that sales figures have rebounded in recent months in both Sweden and Denmark, which is expected to have a positive impact on the revenues for the coming quarters.

Financial development

Profit for the fourth quarter 2020/2021 amounts to SEK -4.4 (-4.9) million and the total cost for the period amounts to SEK -5.9 (-5.7) million, which represents an increase of SEK 0.2 million (2%). Profit for the full year 2020/2021 amounts to SEK -24.6 (-17.7) million and the total cost mass for the full year amounts to SEK -29.0 (-21.8) million, which represents an increase of SEK 7.2 million (33%), as a result of expanded activities. The cost base is expected to increase in the coming periods as the business gears up in scope due to the Phase III trial.

Liquidity

NextCell's cash equivalents as of August 31, 2021 amounted to SEK 139.2 (22.0) million. Total cash flow for the fourth quarter 2020/2021 amounted to SEK -11.6 (16.3) million. Cash flow from operating activities for the fourth quarter is SEK -4.3 (-4.8) million. Cash flow for the entire financial year amounted to SEK 117.2 (1.8) million, of which cash flow from operating activities amounts to SEK -24.1 (-17.3) million. The updated strategy of the ProTrans diabetes study programme reduces the capital requirement in the short term. The company asses that is has financing to run the business with the planned scope of activities for at least three years to come.

Solidity

The company's solidity ratio as of August 31, 2021 was 96.4 (88.1) %.

The share and the largest shareholders

The company's share is listed on First North Growth Market and traded under the ticker "NXTCL". In April 2021, a directed share issue was carried out, which meant that the share capital increased by SEK 136,666.53 by issuing 666,666 shares. As of May 31, 2021, after registration of the directed share issue, the number of shares amounted to 34,379,523 and the share capital to SEK 7,047,802,215. The average number of shares in the fourth quarter was 34,379,523 (22,011,081) and the average number of shares for the full year 2020/2021 was: 30,411,847 (19,864,756). All shares are of the same type and denominated in Swedish kronor (SEK).

As of August 31, 2021, the number of shareholders amounted to approximately 5,050 (3,800). The ten largest shareholders held shares corresponding to 46.5% of the total.

The list below shows the ten largest shareholders in NextCell as of 31/08/2021

NAME	NO. OF SHARES	VOTES AND CAPITAL (%)
Diamyd Medical AB	4 283 861	12.46
Försäkringsbolaget Avanza Pension	3 663 679	10.66
Anders Essen-Möller*	2 518 909	7.33
Ålandsbanken	1 211 585	3.52
Pabros AB	847 452	2.46
Christer Jansson	824 743	2.40
Consensus Sverige Select	666 666	1.94
Nordea Livförsäkring i Sverige AB	663 248	1.93
Konstruktions och Försäljningsaktiebolaget	650 000	1.89
Nordnet Pensionsförsäkring AB	649 256	1.89
In total	**15 979 399**	**46.48**

** In addition to Chairman of the Board, Anders Essen-Möller's directly registered holdings, this item includes holdings of 4.08 percent managed in Avanza Pension.*

Accounting principles for the preparation of thise Year-End Report

The year-end report has been prepared in accordance with the Annual Accounts Act and BFNAR 2012:1 Annual Report and Consolidated Accounts ("K3") and in accordance with BFNAR 2007:1 ("Voluntary Interim Reporting"). For further information on accounting policies, we refer to NextCell's Annual Report for 2019/2020.

Auditor's review

The year-end report has not been reviewed by the Company's auditor.

Certified adviser

Companies affiliated with Nasdaq First North Growth Market require a Certified Adviser. NextCell has appointed FNCA Sweden AB as Certified Adviser, 08-528 00 399, info@fnca.se.

Financial calendar

The company prepares and publishes a financial report at the end of each quarter. Upcoming reports and events are planned as follows:

Annual Report	2021-11-03
Annual Meeting	2021-11-24

Publication of the Year-End Report

Huddinge, 29 October 2021
NextCell Pharma AB

Board of Directors and CEO

Anders Essen-Möller
CHAIRMAN OF THE BOARD

Camilla Sandberg
BOARD MEMBER

Hans-Peter Ekre
BOARD MEMBER

Edvard Smith
BOARD MEMBER

Mathias Svahn
CHIEF EXECUTIVE OFFICER

10.

Income statement

(SEK)	2021-06-01 2021-08-31	2020-06-01 2020-08-31	2020-09-01 2021-08-31	2019-09-01 2020-08-31
Operating Income				
Net income	1 149 669	767 498	3 912 017	3 564 701
Other operating income	230 909	74 756	543 027	601 422
Total Operating Income	**1 380 578**	**842 254**	**4 454 044**	**4 166 123**
Operating Expense				
Materials and goods	-1 822 936	-1 995 702	-9 938 378	-6 765 340
Other external costs	-2 026 092	-1 662 080	-8 501 148	-7 172 686
Personnel costs	-2 087 307	-1 957 817	-10 434 614	-7 506 910
Depreciation	-122 178	-105 762	-437 020	- 397 102
Other operating expenses	-5 065	-6 133	-55 905	-26 453
Total operating expense	**-6 063 578**	**-5 727 495**	**-29 276 065**	**-21 868 490**
Operating result	**-4 683 000**	**-4 885 241**	**-24 821 021**	**-17 702 367**
Financial income and expenses				
Interest income	214 845	14 341	271 839	30 508
Interest expenses and similar expenses	-6 692	-6 449	-7 573	-8 838
Total financial items	**208 153**	**7 892**	**264 266**	**21 670**
Result before tax	**-4 474 847**	**-4 877 349**	**-24 556 755**	**-17 680 697**
Taxes				
Tax expense for the period	0	0	0	0
Net result for the period	**-4 474 847**	**-4 877 349**	**-24 556 755**	**-17 680 697**

11.

Balance sheet

(SEK)	2021-08-31	2020-08-31
ASSETS		
Non-current assets		
Tangible non-current assets		
Property, plant and equipment	1 723 492	1 340 186
Inventories, tools and installations	1 179 950	1 274 346
	2 903 442	**2 614 532**
Financial assets		
Shares and interest in other companies	5 114 736	-
Other long-term receivables	1 128 192	1 128 193
	6 242 928	**1 128 193**
Total non-current assets	**9 146 370**	**3 742 725**
Current assets		
Current receivables		
Trade receivables	1 390 571	820 235
Other receivables	309 974	454 011
Prepaid expenses and accrued income	5 611 635	2 798 783
	7 312 180	**4 073 028**
Liquid assets	**139 167 921**	**21 958 336**
Total current assets	**146 480 101**	**26 031 364**
TOTAL ASSETS	**155 626 471**	**29 774 089**

Balance sheet

(SEK)	2021-08-31	2020-08-31
EQUITY AND LIABILITIES		
Equity		
Restricted equity		
Share capital	7 047 802	4 796 658
Non-restricted equity		
Profit or loss brought forward	-28 827 505	-11 146 808
Shareholders surplus	196 429 502	50 249 300
Result for the period	-24 556 755	-17 680 697
	143 045 242	**21 421 795**
Total equity	**150 093 044**	**26 218 453**
Liabilities		
Long-term liabilities		
Other long-term liabilities	1 576 433	1 380 802
Current liabilities		
Trade payable	1 281 459	477 603
Other liabilities	628 695	176 569
Prepaid income accrued expenses	2 046 839	1 520 662
	3 956 994	**2 174 834**
Total liabilities	**5 533 427**	**3 555 636**
TOTAL EQUITY AND LIABILITIES	**155 626 471**	**29 774 089**

12.

Cash flow statement

(SEK)	2021-06-01 2021-08-31	2020-06-01 2020-08-31	2020-09-01 2021-08-31	2019-09-01 2020-08-31
	3 MONTHS	3 MONTHS	12 MONTHS	12 MONTHS
Operating activities				
Operating profit/loss	-4 683 000	-4 885 241	-24 821 021	-17 702 367
Non-cash flow items				
Depreciation	122 178	105 762	437 020	397 102
Revenue from disposal of assets	-	-	-	-28 883
Interest received	214 845	14 341	271 839	30 508
Interest paid	-6 692	-6 449	-7 573	-8 838
Cashflow from operating activities before changes in working capital	**-4 352 669**	**-4 800 470**	**-24 119 735**	**-17 312 478**
Changes in working capital				
Increase / decrease in receivables	-2 022 686	-640 210	-3 239 152	-1 004 349
Increase / decrease in payables	508 783	-293 544	803 856	-944 231
Increase / decrease in other short-term payables	-241 534	213 670	977 903	301 384
Total of working capital	**-1 755 437**	**-720 084**	**-1 457 393**	**-1 647 196**
Net cash flow from operating activities	**-6 108 106**	**-5 520 554**	**-25 577 128**	**-18 959 674**
Investing activities				
Investments in material and immaterial assets	-	-	-725 930	-787 113
Sale of fixed assets	-	280 000	-	280 000
Investments in financial assets	-5 113 334	-	-5 114 334	-82 900
Net cash flow from investing activities	**-5 113 334**	**280 000**	**-5 840 264**	**-590 013**
Financing activities				
Long-term liabilities	-124 064	280 116	195 631	441 216
New issue	-	25 100 028	164 717 835	25 100 028
Cost related to the new issue	-240 418	-3 794 206	-16 286 489	-4 161 206
Net cash flow from financing activities	**-364 482**	**21 585 938**	**148 626 977**	**21 380 038**
Cash flow for the period				
Cash and cash equivalents at beginning of period	150 753 843	5 612 952	21 958 336	20 128 185
Change in cash and cash equivalents	-11 585 922	16 345 384	117 209 585	1 830 151
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**139 167 921**	**21 958 336**	**139 167 921**	**21 958 336**

13.

Statement of changes in equity

	SHARE CAPITAL	BALANCED RESULT	SHARE PREMIUMS	NET RESULT OF THE PERIOD	TOTAL EQUITY
Opening balance 2019-09-01	**3 924 539**	**6 850 981**	**30 182 598**	**-17 997 789**	**22 960 329**
Disposition from AGM		-17 997 789		17 997 789	0
New issue	872 120		24 227 908		25 100 028
Costs related to the new issue			-4 161 206		-4 161 206
Result				-17 680 697	-17 680 697
Closing balance 2020-08-31	**4 796 658**	**-11 146 808**	**50 249 300**	**-17 680 697**	**26 218 453**

	SHARE CAPITAL	BALANCED RESULT	SHARE PREMIUMS	NET RESULT OF THE PERIOD	TOTAL EQUITY
Opening balance 2020-09-01	**4 796 658**	**-11 146 808**	**50 249 300**	**-17 680 697**	**26 218 453**
Disposition from AGM		-17 680 697		17 680 697	0
New issue	2 251 144		162 466 691		164 717 835
Cost related to the new issue			-16 286 489		-16 286 489
Result				-24 556 755	-24 556 755
Closing balance 2020-08-31	**7 047 802**	**-28 827 505**	**196 429 502**	**-24 556 755**	**150 093 044**

Company information

Company name: NextCell Pharma AB (Publ.)
Organization number: 556965-8361
Legal corporate form: Publikt aktiebolag
Place: Huddinge

Trading place: Nasdaq First North Growth Market
Address: Novumhuset Hälsovägen 7, 141 57 Huddinge
Telephone: +46 8 735 55 95
Web page: www.nextcellpharma.com | www.cellaviva.se