# Interim report 1 for the stem cell company

# NextCell Pharma AB

## September 2020 – November 2020

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 stem 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

# Innehållsförteckning



# 01.

# Interim Report Q1

**"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.**

## First quarter (2020-09-01 until 2020-11-30)

- Operating income amounted to SEK 1 148 187 (1 222 087)
- Operating result amounted to SEK -17 680 697 (-17 997 787)..
- Earnings per share* amounted to SEK -0,23 (-0,20).
- Cash and bank amounted to SEK 16 810 206 (15 715 418). After the end of the period, in December 2020, the Company received an additional SEK 150 million (approximately SEK 135 million after deductions for transaction costs) as a result of a rights issue.
- Solidity** amounted to 84,9 (84,6) %.

**Result per share: operating results divided by the average number of shares. Average number of shares for the first quarter of 2020/2021: 23 398 334 (19 144 092) shares. Number of shares in NextCell as per November 30th, 2020: 23 398 334 (19 144 092) shares.*
*** Solidity/Equity ratio: shareholders' equity of the balance sheet total.*

## Significant events during the first quarter of 2020/2021

- NextCell announced, in early September, a significant effect in the phase II study ProTrans-2. The patients treated with one dose of the stem cell product ProTrans™ (ProTrans) did maintained a statistically significantly higher insulin production after a 12-months period compared with patients treated with placebo (p-value <0.05).

- NextCell announces in late October that the application for clinical trial of COVID-19 patients with ProTrans has been approved by both the Ethics Committy and the Swedish Medical Product Agency. The study will be conducted at the University Hospital in Örebro in collaboration with the Department of Clinical Trials and Karolinska Trial Alliance.

- NXTCL publishes a notice to attend the Annual General Meeting. Notice with suggested resolutions is available on the Company´s website (www.nextcellpharma.com).

- NextCell announces that it, in collaboration with other project members, including SCINUS Cell Expansion, now officially has started the previously communicated Eurostars project, Bioscale, with the aim of developing a cost-effective expansion technology in cell culture. NextCell's stem cell product ProTrans will be used to test and validate the capacity of the SCINUS bioreactor to provide an optimized method for cost-effective cell production. NextCell has been granted a Eurostar grant of SEK 5 million and will contribute the same amount in own work. The total budget for the project is SEK 28 million.

- NextCell has entered into an agreement with Professor Per-Ola Carlsson, at Uppsala University Hospital and Uppsala University, with the aim of contributing ProTrans for the treatment of children and adolescents with type 1 diabetes, within the framework of clinical drug trials. The study, which is in the planning stage, is part of NextCell's strategy to support academic groups with drugs to be able to evaluate ProTrans for a wider use.

- The Board of Directors of NextCell announces its intention to resolve on a fully guaranteed rights issue of up to approximately SEK 150 million for the Company’s existing shareholders. The Board of Directors’ intent to resolve on the Rights Issue requires that the shareholders at the Annual General Meeting authorizes the Board of Directors to resolve on share issues. In the notice convening the Annual General Meeting, which

- The Board of NextCell announces its intention to resolve on a fully guaranteed rights issue of approximately SEK 150 million, provided that the Annual General Meeting authorizes the Board to decide on a new rights issue. The Company's largest shareholder, Diamyd Medical AB, has undertaken to subscribe for its pro rata share, amounting to a total of approximately SEK 19 million. Furthermore, parts of the Company's Board and senior executives have entered into subscription undertakings amounting to approximately SEK 5.3 million. In total, the rights issue is covered by subscription undertakings to 45 percent and by issue guarantees to 55 percent.

- NXTCL holds its Annual General Meeting. Communique with a summary of decided resolutions is available on the Company´s website (www.nextcellpharma.com).

- The Board decides, based on the authorization from the Annual General Meeting, to carry out the previously proposed rights issue of SEK 150 million.

## Significant events after the reporting period

- Due to the decided rights issue, a prospectus is published at the beginning of December and a subscription period begins.

- NextCell publishes, in early December, results from the clinical trial ProTrans-Repeat. The primary endpoint, safety, is met. There were no severe adverse events recorded during the 12-month follow-up period after a second dose of ProTrans Furthermore, a strong tendency of sustained efficacy was observed in the three patients receiving high dose ProTrans.

- NextCell announces that an observational study, ProTrans-OBS, has been approved by the Swedish Ethical Review Board for long-term follow-up of patients previously participating in the ProTrans-2 clinical trial. The study is conducted by professor Per-Ola Carlsson, at Uppsala University.

- NextCell announces the outcome in the rights issue. The issue was oversubscribed and, thus, NextCell is provided with the full issue amount of SEK 150 million before issue costs. The oversubscription means that no issue guarantees have been used.

- The Board of Directors of NextCell resolves, based on the authorization from the Annual General Meeting, on a directed issue of 286 666 new shares to Polski Bank Komórek Macierzystych SA (“ PBKM ”), Europe's largest stem cell bank and an important partner to the Company. The subscription price in the share issue amounts to SEK 15 per new share, giving the Company approximately SEK 4.3 million in issue proceeds.

# 02.

# NextCell Pharma – a part of the Stem Cell Revolution

**NextCell is active within the area of stem cell research, a field that could revolutionize the way diseases are treated in the future. The Company develops novel cell therapies based on mesenchymal stem/stromal cells (MSCs) derived from the umbilical cord. In the Company's clinical trials ProTrans™ has been shown to be both safe and efficacious in maintaining a patient's ability to produce their own insulin.**

NextCell was founded in 2014 by researchers at Karolinska Institutet, initially under the name Cellaviva AB. NextCell's business concept is to develop and commercialize stem/stromal cell therapies based on the Company's novel selection algorithm (patent pending). Beside generating stromal cell therapies, NextCell operates Cellaviva, Sweden's first and the Nordic region's largest stem cell bank. Via Cellaviva, parents are offered the opportunity to save their new born baby´s hematopoietic and mesenchymal stem cells, extracted from the umbilical cord, for future medical needs. Cellaviva is the only stem cell bank in Sweden with a permit from the Swedish Inspection for Health and Care (IVO).

With the proprietary selection algorithm, advanced cell therapies for autoimmune and inflammatory diseases are evaluated. NextCell's drug candidate, ProTrans, is based on mesenchymal umbilical cord stem/stromal cells, selected by the algorithm. Initial focus has been the treatment of type 1 diabetes.

In September 2020, positive results from NextCell's clinical phase II trial, ProTrans-2, were presented. The study showed that patients treated with one dose of ProTrans maintained a statistically significant elevated production of insulin after a twelve-month period compared with the patients treated with placebo, thus achieving the study's primary endpoint. Furthermore, in December 2020, results from the follow-up study, ProTrans Repeat, were published. In addition to demonstrating the primary endpoint, a strong tendency of sustained efficacy was observed in the patients receiving high dose ProTrans. Based on these successful results in phase II, NextCell's intention is to take ProTrans to market approval via a larger phase III study, ProTrans-3.

Type-1 diabetes has been selected as the first indication for ProTrans. In the United States alone, more than 60,000 people are diagnosed with type 1 diabetes each year, and existing therapies focus only on treating the symptoms. **One of the 's goals is for ProTrans to become the first treatment targeting the underlying disease in type 1 diabetes.**

# 03.

# CEO comments

**For a start, I want to thank all the shareholders who participated in the recently completed rights issue. SEK 135 million - after deductions for issue related costs - means that NextCell now can fully focus on developing treatments for diseases with great medical need, and thus build value for our shareholders. Also, the completion of an oversubscribed share issue of this size under prevailing market conditions is a major milestone. A strength that may take ProTrans™ (ProTrans) all the way to the market.**

Your trust makes it possible for NextCell to conduct a phase III study with ProTrans. There are only a few clinical trials with mesenchymal stem cells that have reached phase III. Together with our study teams, we have managed to demonstrate ProTrans' efficacy and safety in ProTrans-1, ProTrans-2 and ProTrans-Repeat. Importantly, these studies were completed on schedule and within budget.

Preparations for Phase III are proceeding according to plan. There is feverish activity in the Company right now and we have strengthened the organisation with additional employees and contracted an international CRO to run the study. It is a giant operation that means gradually increased costs. These changes have been absolutely crucial, ensuring that the study is optimally designed and therefore we must allow the process to take some time. Although my hope is that we will get the study both approved and started within 2021.

The study design of ProTrans-3 will be very similar to ProTrans-2. Patients aged 18-40, diagnosed within the last two years will be able to participate and the therapeutic effect will be evaluated one year after treatment. For this particular group of patients, we feel confident that ProTrans has an effect up to 12 months post treatment. However, questions remain regarding the longevity of the therapeutic effect and the feasibility of treating children and adolescents. To get answers to these questions, further studies are planned. We are following the participants in ProTrans-2 for a total of five years in an observational study, ProTrans OBS, and in ProTrans-Repeat we will the same for the participants who completed ProTrans 1. Furthermore, Professor Per-Ola Carlsson is planning a study similar to ProTrans1/2 for treatment of children and adolescents where NextCell will contribute with ProTrans drugs.

The first quarter of our financial year coincides with the second wave of COVID-19. Unfortunately, the pandemic during the autumn has affected the possibility of carrying out stem cell collections, which has led to a lack of the usual increase in Cellaviva's sales. Despite the circumstances, the influx of customers has been relatively good but, unfortunately due to increasingly strict restrictions on the maternity wards, many collections have not been practically feasible.

COVID-19 has also led to NextCell accelerating the clinical trial program for the treatment of hyper inflammation of the lungs. We know that a large part of ProTrans stem cells get stuck in the small blood vessels in the lungs, which makes the lung an excellent target for treatment. Hyper inflammation of the lungs can be caused by various traumas and infections, such as corona virus. A lung study is within our area of interest and the large and acute medical need for this type of treatment has pushed us to accelerate this development. ProTrans19 +, a Phase Ib study, has been approved by the Medical Products Agency and we hope to be able to start treatment of patients with severe COVID-19 during the current quarter. In addition to the scientific rationale

and the extensive medical need, the choice to start a clinical trial in hyperinflammation of the lungs caused by corona virus infection is also a strategic decision to show the breadth of ProTrans potential for immunomodulatory treatment. Diabetes is a severe chronic autoimmune disease, but as long as the patients have good control of their diabetes, they often feel relatively well for several years. COVID-19 is an acute viral infection that in severe cases can lead to hyperinflammation, intensive care and in the worst cases, death. Two completely different conditions due to an immune system that has become unbalanced, and thus potentially benefiting from the immunomodulatory therapeutic effects of ProTrans.

Finally, I would like to thank all the patients who participated in our clinical trials. It has been three years since the first patient with type 1 diabetes, a young man, received the world's first dose of ProTrans. Since that time, I have received calls and e-mails from people who would like to be part of a study with ProTrans. I hope for your continued confidence during the implementation of ProTrans-3.

**Mathias Svahn, Ph.D.**
*CEO NextCell Pharma AB*

## 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.

# 04.

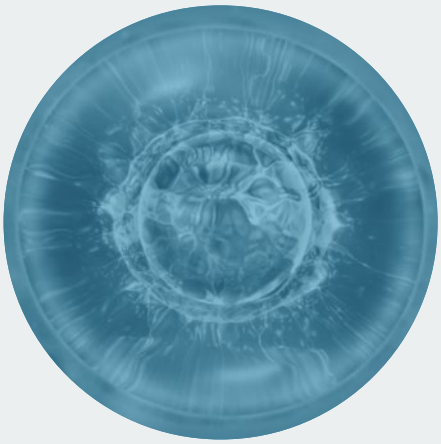
# Product Portfolio

**NextCell´s product portfolio is based on mesenchymal stem cells from Wharton's Jelly (WJMSCs), ie the gelly that is found around the blood vessels in the umbilical cord tissue. Mesenchymal stem cells have an immunomodulatory ability, a feature that can be useful in a variety of areas where there is today great potential for improvement, such as in treatment of autoimmune conditions and rejection in transplants.**

Currently, there are a number of approved treatments with mesenchymal stem cells from, for example, adipose and bone tissue, but no established method of treatment with mesenchymal stem cells from umbilical cord tissue. On the other hand, there are a large number of clinical trials in stem cells from umbilical cord tissue are ongoing globally.

**The basis for NextCell's stem cell therapies is the Company's proprietary selection algorithm, a patent - pending method for selecting stem cells with the best efficiency and potency.** The method is an overall assessment of multiple functional potency assays for identifying optimal donors and cells for the manufacturing of ProTrans™ (ProTrans). NextCell's advanced selection approach ensures higher potency and efficacy compared to other applications in stem cell therapy and has the ability to easily upscale. It also results in a strong safety profile with few adverse events. **The selection Algoritm is currently protected by three patent pending families.**

Furthermore, NextCell's competitive strength also lies in the use of stem cells from umbilical cord tissue. It serves as a potent cell source, capable of rapid expansion. NextCell's stem cell products are allogeneic, which means that donated stem cells, not the patient's own, are used.



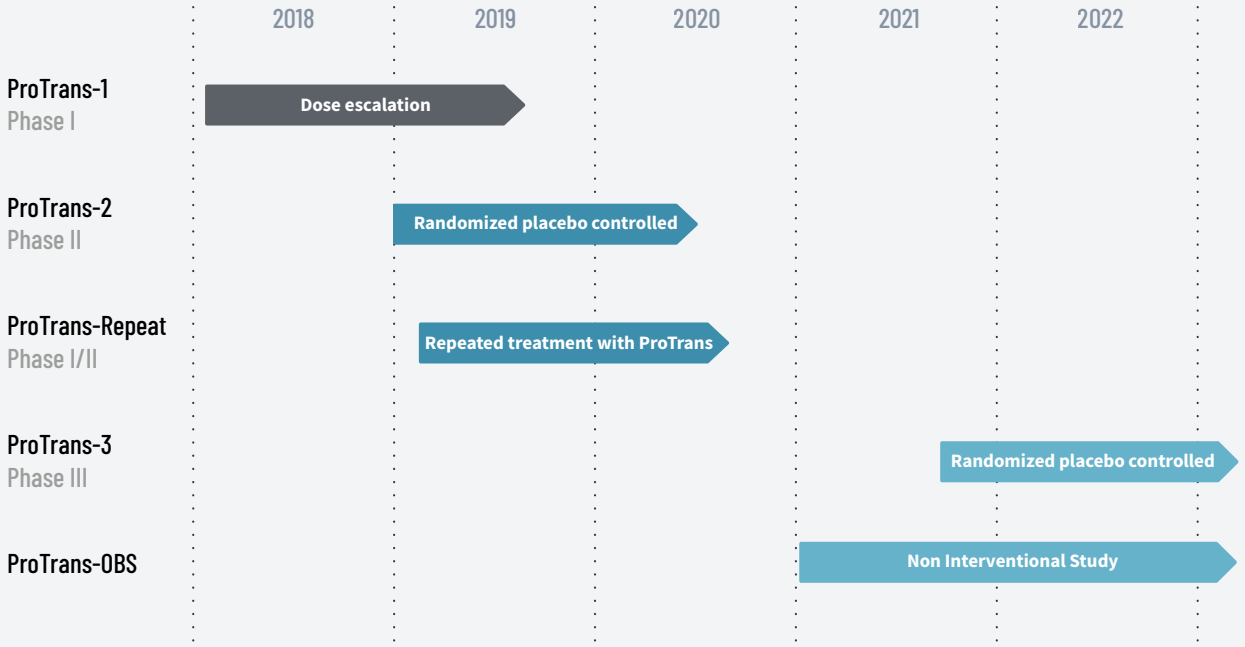
# 05.

## ProTrans™

**ProTrans™ (ProTrans) is NextCell´s lead candidate, based on the selection algorithm and developed for the treatment of type-1 diabetes. Type-1 diabetes is a chronic autoimmune condition in which the immune system is attacks the insulin producing cells in the pancreas. The causes of this autoimmune reaction are not known and are not linked to modifiable lifestyle factors. Today, there is no cure and it cannot be prevented. About 5–10 percent of all the patients with diabetes have the type-1 form, with the disease usually diagnosed in children and young adults. About the same number have an adult form of autoimmune diabetes, LADA (Latent Autoimmune Diabetes in the Adult) and a total of about 80 million people live with some form of autoimmune diabetes.**

ProTrans is manufactured from umbilical cord, donated for this specific purpose, and from these cords a large amounts of stem cells are grown. The expanded stem cells are frozen and can, when needed, be thawed, and given to the patient directly after diagnosis. ProTrans is manufactured by a contract manufacturing organization (CMO) accordingly to NextCell's criteria. The goal is to reprogram the immune system to accept the body's own insulin producing cells. ProTrans reduces the immune system attack, and thus insulin production is preserved. By restoring the patient's innate insulin producing ability, the need for insulin treatment is reduced.

Since safety and immunomodulatory effects have been shown in phase I and phase II of the diabetes study, it is likely that ProTrans can also be effective for other types of inflammatory and autoimmune diseases. Sales or out-licensing of the selection algorithm or ProTrans can take place per indication, i.e. a platform technology with a possibility to generate several transactions. NextCell will, in parallel with the clinical trial program for type 1 diabetes, conduct a study where Covid-19 patents are treated with ProTrans stem cells. The severe stage of COVID-19 is when the immune system becomes hyperactive and attacks organs including the lungs. The hypothesis is to treat patients before they reach this life-threatening condition.




**Note:** In order to simplify for the reader, the study titles' short names have 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 the patients in the dose scaling section have undergone another treatment with ProTrans, EudraCT no: 2018-004158-11

## ProTrans™ – carefully selected stem cells

The drug candidate ProTrans™ (ProTrans) is a mesenchymal stromal/stem cell (MSC) product from umbilical cord cells. The cells are carefully selected using NextCell's selection algorithm (patent pending).

In the laboratory, a variety of advanced analyses are performed to evaluate the function of cells and how they affect the immune system. The results are entered into the selection algorithm that calculates the cells' combined ability to attenuate an overactive immune system through several mechanisms of action.

## ProTrans™ – biological intelligence

The immune system consists of a variety of cell types that are activated or inactivated by a multitude of different signalling molecules. In autoimmune diseases, this delicate balance has been disrupted and the immune system attacks the body's own cells, resulting in inflammation. This progression varies between individuals and can change over time.

ProTrans utilizes the body's own way of restoring balance. Mesenchymal stem cells immediately respond to the pathological inflammatory signalling in the environment and secrete signalling molecules to counteract the inflammation.

## ProTrans™ – industrially designed cell therapy

NextCell has developed ProTrans to reach all the way to the patient. Umbilical cord stem cells can be grown in large quantities and as they are non-invasively harvested from dispensable material, the supply of raw materials is virtually unlimited.

ProTrans therapy is simple and safe and can be performed at the health center (vårdcentralen). ProTrans is delivered as frozen cells in a small bag. ProTrans is thawed, and the bag of cells is then paired with a standard infusion bag. The stem cells are gently mixed with a saline solution before being given as an infusion into the arm fold. The treatment is cost-effective as NextCell can produce large production batches, can stably store frozen ProTrans for extended periods, and treatment is uncomplicated and non-invasive.

# 06.

# Clinical trials with ProTrans™ stem cells

### ProTrans for the treatment of type 1 diabetes

**NextCell is conducting a clinical trial program with the drug candidate ProTrans™ (ProTrans) for treatment of patients with type 1-diabetes. ProTrans-1 (phase I) and ProTrans-2 (phase II) have been completed with positive results. The patients included are all between the ages of 18-40, have been diagnosed with type 1 diabetes within the past two or three years, and still retain some of their own insulin production.**

The clinical trails have been conducted at the Karolinska Trial Alliance Phase I unit under the direction of Professor Per-Ola Carlsson, from Uppsala University, as Principal Investigator. Professors Ulf Smith and Anders Fasth from Göteborg University, and Professor Åke Lernmark from Lund University, together form the Data Safety Monitoring Board.

### ProTrans-1

ProTrans-1 was started in January 2018 as a phase I study, evaluating ProTrans™ (ProTrans) safety and it´s impact on the patient's own insulin production. The study included a total of nine patients treated with low, medium and high dose. Results of the study were published on December 4, 2019 and showed a statistically significant difference in own insulin production between the different patient groups. The patients in the high and medium dose cohort had maintained a higher insulin production compared to the patients in the low dose cohort.

### ProTrans-2

ProTrans-2 was a randomized, double-blinded, placebo-controlled phase II study with the effecacy as primary end point. 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-blinded ensured that neither the doctors or patients knew if they had received active treatment or placebo during the 12-month follow-up period. The results showed that the patients treated with ProTrans had maintained a statistically significantly higher insulin production after a 12-month period compared with the patients treated with placebo (p-value <0.05).

### ProTrans-3

Given positive results in ProTrans-2, NextCell is planning to submit an application for a phase III study, ProTrans-3, during 2021. ProTrans-3 will be a larger phase III clinical study, and the intention is that this study will form the basis for a conditional market approval.

### ProTrans-Repeat

ProTrans-Repeat was started in May 2019 and is a continuation study of ProTrans-1/2 with the aim of obtaining data on repeated treatment, ie verifying whether repeated treatment can increase or maintain any potential effect of ProTrans over a long period of time with retained safety. The study includes the nine patients treated in the ProTrans-1 study's dose escalating part as well as another nine patients that serve as a control group. The efficacy is measured by comparing the patient's ability to produce insulin before treatment with 12 months after treatment with the repeated dose of ProTrans. Patients are followed for five years after treatment is completed. The last patient in ProTrans-Repeat was treated in September 2019 and positive data were published in December 2020. Primary endpoint, safety, was met. No severe adverse events were recorded during the 12-month follow-up period after a second dose of ProTrans. Furthermore, a strong tendency of sustained efficacy was observed in the three patients receiving high dose ProTrans.

### ProTrans-OBS

The observational study, ProTrans-OBS, was approved by the Swedish Ethical Review Board in December 2020 and the start is scheduled to the first quarter of 2021. The trial is a follow-up of the clinical trial ProTrans 2 and patients that completed ProTrans-2 are asked to participate in semi-annual follow-up of safety and efficacy over a four-year period. The OBS study is conducted by Professor Per-Ola Carlsson at Uppsala University and is a non-intervention study, ie. the patients included will only be followed up, not be treated with aditional doses of ProTrans. As stated above, the ProTrans-Repeat study showed both efficacy and safety over a two-year period where an additional high dose of ProTrans was given after 12 months. The long-term effect of a single infusion compared to two infusions is evaluated by running the two studies, ProTrans-Repeat and ProTrans-OBS, in parallel.

### ProTrans for the Treatment of Covid-19 and Other Respiratory Diseases

NextCell has an approval from both the Swedish Ethical Review Board and the Medical Products Agency to start ProTrans-19+, a clinical drug trial where COVID-19 patients are treated with the drug candidate ProTrans. ProTrans is an immunomodulatory stem cell therapy and this mechanism is believed to be effective in other autoimmune diseases and inflammatory conditions in addition to type 1 diabetes. 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 before they reach this life-threatening condition. In this open phase 1b study, a total of three groups of each three patients will be treated with different doses of ProTrans. The study will be carried out at the University Hospital in Örebro in collaboration with the Department of Clinical Trials and Karolinska Trial Alliance.

## Milestones achieved

### ProTrans-1

| | |
|---|---|
| **2019-12-04** | Interim results published with positive effect |
| **2019-09-24** | All patients in the dose escalation phase have now completed the trial |
| **2018-10-14** | All three patients in the high-dose-cohort treated (nine patients have been treated in total) |
| **2018-01-03** | First patient treated |
| **2017-11-28** | Initiation meeting at Karolinska Trial Alliance, Huddinge |
| **2017-10-17** | Permission granted by the Medicinal Product Agency |
| **2017-07-24** | Clinical trial application submitted |

### ProTrans-2

| | |
|---|---|
| **2020-09-08** | Positive data with statistical significance are published |
| **2020-06-08** | All patients have now completed the trial |
| **2019-06-20** | Final patient treated in ProTrans-2 |
| **2019-01-30** | First two patients have been treated in ProTrans-2 |
| **2018-10-25** | Approval by the Data and Safety Monitoring board to proceed with the second part of the trial |

### ProTrans Repeat

| | |
|---|---|
| **2020-12-10** | Positive data with proven efficacy and safety are published |
| **2019-10-01** | Last patient in ProTrans-Repeat's active treatment group treated. |
| **2019-06-19** | First patient treated. |
| **2019-05-09** | Permission granted by the Swedish Medicinal Product Agency. (Läkemedelsverket). |

# 07.

# Cellaviva – from birth to life

**NextCell operates, in addition to its research, Sweden's first and Nordic region's largest biobank for stem cells, Cellaviva. Cellaviva offers parents the service to store stem cells, hematopoietic from umbilical cord blood and mesenchymal from the umbilical cord, at the time of birth.**

After the expansion to Denmark, and with a customer base throughout Scandinavia, the business has grown to become a market leader in stem cell banking throughout Scandinavia, and the only stem cell bank with permission from the Swedish Inspectorate for Health and Care (IVO).

Cellaviva launched its product in September 2015 and today, the Swedish market still can be regarded as relatively immature. However, abroad stem cell banking has been around for decades and is an established and widespread service globally. The market penetration for stem cell savings differs a lot between different countries. Singapore is at the top with tissue saved for over 20 percent of the births, while European countries are usually below 5 percent. NextCells assessment is that Sweden is far behind and that awareness of the presence of stem cells in the unbilical cord is low.

In 1988, the first stem cell transplant with umbilical cord blood cells was performed. Previously, the only stem cell source was bone marrow. Collecting stem cells from bone marrow is an extensive and invasive procedure and must be done close to the time that the transplant will be performed. Birth is a unique opportunity to collect stem cells from the umbilical cord using a non-invasive procedure from dispensable tissue. In addition, the stem cells are both unaffected by environmental factors and are most effective at birth.

Extensive research with stem cells is being conducted. Currently, globally more than 2 300* clinical trials are ongoing with experimental treatments for diseases as cancer, diabetes, cerebralpalsy, Alzheimer´s, multiple sclerosis, ALS and more. The goal is to develop new ways of treating today incurable diseases.

*www.clinicaltrials.com

**Today, stem cells** are used to treat a variety of severe diseases, such as blood cancers and immune system disorders. If needed, banked stem cells from the newborn baby can make treatment of severe illnesses easier, and shorten the waiting times for therapy, because matching stem cells are already available. In some cases, family members can also be treated with the stem cells from the newborn baby.

**Read more about** family saving of stem cells at *https://cellaviva.se/*

# 08.

# Development in numbers during the period

## CFO Sofia Fredrikson comments on the financial development

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

### Operating income

Operating income for the first quarter of 2020/2021 amounts to SEK 1,1 (1,2) million, where SEK 1,0 (1,1) million relates to income from Cellaviva's operations. As a result, revenues decreased by SEK 0,1 million, corresponding to -9% between the periods. Revenues related to Cellaviva have shown steady growth over the past two years. However, during the past quarter, a slowdown has been noted which can be explained by the current pandemic. Partly due to restrictions that disable some of the planned stem cell collections but also as a result of the economic crisis that leads potential customers to refrain from investing in stem cell savings.

### Financial development

The result for the first quarter 2020/2021 amounts to SEK -5,4 (-3,8) million. The total cost base for the period amounts to SEK -6,6 (-5,0) million, an increase of SEK 1,6 million (33%) The increase is in line with a budget and is mainly traced to the item Other external costs. The costs are expected to increase in coming periods as the business shifts up in scope due to the planned phase III study.

### Liquidity

NextCell's cash and cash equivalents as of November 30, 2020 amounted to SEK 16,8 (15,7) million. Total cash flow for the first three months 2020/2021 amounted to SEK -5,1 (-4,4) million. Cash flow from operating activities amounted to SEK -5,1 (-4,3) million. Thus, cash flow from operating activities has increased by SEK 0,8 million, corresponding to 19%, which is in line with expectations and budget as the business gradually is scaling up due to the planned Phase III study. After the end of the period, in December 2020, a rights issue was carried out which provided the Company with SEK 150 million, approximately SEK 134.5 million after deduction of transaction costs.

### Solidity

The solidity ratio as per November 30, 2020 amounted to 84,9 (84,6) %.

### The share and the largest share holders

The Company's share is listed on First North Growth Market and is traded under the ticker "NXTCL". As of November 30, 2020, the number of shares was 23 398 334 and the share capital was SEK 4 796 658,47. The average number of shares during the fourth quarter was 23 398 334 (19 144 092). All shares are of the same type and denominated in Swedish kronor (SEK). After the end of the period, in December 2020, a rights issue was carried out, which meant that the share capital increased by SEK 2,055,710,685 by issuing 10,027,857 shares. After registration, the share capital amounts to 6,852,369,155 and the number of outstanding shares amounts to 33,426,191.

As of November30, 2020, the number of shareholders was approximately 3 990 (2 590). The ten largest owners held shares corresponding to 46,4 % of the total number.

**The list below shows the ten largest shareholders in NextCell Pharma as per 2020-11-30**

| NAME | SHARES | VOTES AND CAPITAL (%) |
|---|---|---|
| Diamyd Medical AB | 2 998 703 | 12,82 |
| Anders Essen-Möller* | 2 284 534 | 9,76 |
| Avanza Pension | 1 782 733 | 7,62 |
| Ålandsbanken | 770 819 | 3,29 |
| Pabros AB | 593 217 | 2,54 |
| Nordnet Pensionsförsäkring | 577 506 | 2,47 |
| Christer Jansson | 507 258 | 2,17 |
| BioAll AB** | 467 931 | 2,00 |
| Konstruktions och försäljningsaktiebolaget | 439 765 | 1,88 |
| Robert Joki | 438 888 | 1,88 |
| **Total** | **10 739 784** | **46,4** |

**In addition to Chairman of the Board, Anders Essen-Möller´s directly registered holdings, this item includes holdings of 4,87 percent managed by Avanza Pension.*

*** BioAll AB is controlled by CEO Mathias Svahn and his relatives. This item also includes Mathias Svahn´s directly registered holdings of 0,29 percent managed through Nordnet Pensionsförsäkring of 0,11 percent.*

## Accounting principles for the preparation of this Year-End Report

The Interim Report has been prepared in accordance with the Annual Accounts Act and BFNAR 2012:1 Annual Report and Consolidated Financial Statements ("K3") and according to BFNAR 2007: 1 ("Voluntary Interim Reporting"). For further information on accounting principles, consult NextCell's Annual Report.

## Auditor's review

The Interim Report has not been reviewed by the Company's auditor.

## Financial calendar

The Company prepares and publishes a financial report each quarter. Upcoming reports are planned as follows:

| | |
|---|---|
| Interim Report 2 | 2021-04-29 |
| Interim Report 3 | 2021-07-30 |
| Year-End Report | 2021-10-29 |
| Annual Report | 2021-11-03 |
| Anual Meeting | 2021-11-24 |

## Publication of interim report

Huddinge, January 29, 2021
NextCell Pharma AB

**Board of Directors**

**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

# 09.

# Income statement

| (SEK) | 2020-09-01<br>2020-11-30 | 2019-09-01<br>2019-11-30 | 2019-09-01<br>2020-08-31 |
|---|---|---|---|
| **Operating income** | | | |
| Net income | 1 036 846 | 1 137 587 | 3 564 701 |
| Other operating income | 111 341 | 84 500 | 601 422 |
| **Total operating income** | **1 148 187** | **1 222 087** | **4 166 123** |
| | | | |
| **Operating expense** | | | |
| Materials and goods | -2 092 251 | -1 760 794 | -6 765 340 |
| Other external costs | -2 106 039 | -1 199 343 | -7 172 686 |
| Personnel costs | -2 315 955 | -1 926 896 | -7 506 910 |
| Depreciation | -95 638 | -79 623 | -397 102 |
| Other operating expenses | -11 622 | -10 445 | -26 453 |
| **Total operating expenses** | **-6 621 505** | **-4 977 101** | **-21 868 490** |
| | | | |
| **Operating results** | **-5 473 319** | **-3 755 014** | **-17 702 367** |
| | | | |
| **Financial income and expenses** | | | |
| *Interest received* | 0 | 0 | 30 508 |
| *Interest expenses and similar expenses* | 0 | -912 | -8 838 |
| **Total** | **0** | **-912** | **-21 670** |
| | | | |
| **Result before taxes** | **-5 473 319** | **-3 755 926** | **-17 680 697** |
| | | | |
| **Taxes** | | | |
| Tax expenses for the period | 0 | 0 | 0 |
| | | | |
| **Net result for the period** | **-5 473 319** | **-3 755 926** | **-17 680 697** |

# 10.

# Balance sheet

| (SEK) | 2020-11-30 | 2019-11-30 | 2020-08-31 |
|---|---|---|---|
| **ASSETS** | | | |
| **Non current assets** | | | |
| *Tangible non-current assets* | | | |
| Property, plant and equipment | 1 300 131 | 741 358 | 1 340 186 |
| Inventories, tools andinstallations | 1 250 747 | 1 654 658 | 1 274 346 |
| | **2 550 878** | **2 396 016** | **2 614 532** |
| *Financial assets* | | | |
| Other long-term receivables | 1 129 193 | 1 128 193 | 1 128 193 |
| | **1 129 193** | **1 128 193** | **1 128 193** |
| **Total non-current assets** | **3 680 071** | **3 524 209** | **3 742 725** |
| **Current assets** | | | |
| *Current receivables* | | | |
| Trade receivables | 761 602 | 782 787 | 820 235 |
| Other receivables | 494 491 | 384 061 | 454 011 |
| Prepaid expenses and accrued income | 2 687 599 | 2 299 189 | 2 798 783 |
| | **3 943 693** | **3 466 036** | **4 073 028** |
| **Liquid assets** | **16 810 206** | **15 715 418** | **21 958 336** |
| **Total current assets** | **20 753 899** | **19 181 454** | **26 031 364** |
| **TOTAL ASSETS** | **24 433 970** | **22 705 663** | **29 774 089** |

# Balance sheet

| (SEK) | 2020-11-30 | 2019-11-30 | 2020-08-31 |
|---|---|---|---|
| **EQUITY AND LIABILITIES** | | | |
| **Equity** | | | |
| *Restricted equit* | | | |
| Share capital | 4 796 658 | 3 924 539 | 4 796 658 |
| *Non-restricted equity* | | | |
| Profit or loss brought forward | -28 827 505 | -644 003 | -14 599 803 |
| Shareholders surplus | 50 249 300 | 19 679 793 | 53 702 295 |
| Result for the period | -5 473 319 | -3 755 925 | 17 680 697 |
| | **15 948 476** | **15 279 865** | **21 421 795** |
| **Total equity** | **20 745 134** | **19 204 404** | **26 218 453** |
| **Liabilities** | | | |
| *Long-term liabilities* | | | |
| Other long-term liabilities | 1 572 194 | 952 706 | 1 380 802 |
| *Current liabilitie* | | | |
| Trade payable | 708 947 | 1 371 689 | 477 603 |
| Other liabilities | 278 697 | 158 439 | 176 569 |
| Prepaid income accrued expenses | 1 128 998 | 1 018 426 | 1 520 662 |
| | **2 116 641** | **2 548 553** | **2 174 834** |
| **Total liabilities** | **3 688 836** | **3 501 260** | **3 555 636** |
| **TOTAL EQUITY AND LIABILITIES** | **24 433 970** | **22 705 663** | **29 774 089** |

# 11.

# Cash flow statement

| (SEK) | 2020-09-01<br>2020-11-30 | 2019-09-01<br>2019-11-30 | 2019-09-01<br>2020-08-31 |
|---|---|---|---|
| | 3 MONTHS | | 12 MONTHS |
| **Operating activities** | | | |
| Operating profit/loss | -5 473 319 | -3 755 014 | -17 702 367 |
| | | | |
| **Non-cash flow items** | | | |
| Depreciation | 95 638 | 79 623 | 397 102 |
| Revenue from disposal of assets | 0 | 0 | -28 883 |
| Interest received | 0 | 0 | 30 508 |
| Interest paid | 0 | -912 | -8 838 |
| **Cashflow from operating activities before changes in working capital** | **-5 377 681** | **-3 676 303** | **-17 312 478** |
| | | | |
| **Changes in working capital** | | | |
| Increase / decrease in receivables | 129 335 | -397 555 | -1 004 547 |
| Increase / decrease in payables | 231 344 | -50 145 | -944 231 |
| Increase / decrease in other short-term payables | -98 145 | -218 984 | 301 384 |
| **Total of working capital** | **262 534** | **-666 684** | **-1 647 394** |
| | | | |
| **Net cash flow from operating activities** | **-5 115 147** | **-4 342 987** | **-18 959 872** |
| | | | |
| **Investing activities** | | | |
| Investments in material and immaterial assets | -31 984 | 0 | -787 113 |
| Sale of fixed assets | 0 | 0 | 280 000 |
| Investments in financial assets | -1 000 | -82 900 | -82 900 |
| **Net cash flow from investing activities** | **-32 984** | **-82 900** | **-590 013** |
| | | | |
| **Financing activities** | | | |
| Long-term liabilities | 0 | 13 120 | 441 216 |
| New issue | 0 | | 0 |
| Cost related to the new issue | 0 | 0 | 25 100 028 |
| Net cash flow from financing activities | 0 | | -4 161 206 |
| **Kassaflöde från finansieringsverksamheten** | **0** | **13 120** | **21 380 038** |
| | | | |
| **Cash flow for the period** | | | |
| Cash and cash equivalents at beginning of period | 21 958 336 | 20 128 185 | 20 128 185 |
| Change in cash and cash equivalents | -5 148 131 | -4 412 767 | -1 830 151 |
| | | | |
| **CASH AND CASH EQUIVALENTS AT END OF PERIOD** | **16 810 206** | **15 715 418** | **21 958 336** |

# 12.

# Statement of changes in equity

## 2020-08-31

| | SHARE CAPITAL | BALANCED RESULTS | ÖVERKURSFOND | PERIODENS RESULTAT | SUMMA EGET KAPITAL |
|---|---|---|---|---|---|
| | | Share premiums | Net results | 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** |

## 2020-11-30

| | SHARE CAPITAL | SHAREHOLDERS CONTRIBUTION | SHARE PREMIUMS | BALANCED RESULT | 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 | | | | | |
| Cost related to the new issue | | | | | |
| Result | | | | -5 473 319 | -5 473 319 |
| **Closing balance 2020-11-30** | **4 796 658** | **-28 827 505** | **50 249 300** | **-5 473 319** | **20 745 134** |

## COMPANY INFORMATION

**Company name:** NextCell Pharma AB (Publ.)
**Organization number:** 556965-8361
**Legal corporate form:** Public limited Company
**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