

Interim report 2 for the stem cell company

# NextCell Pharma AB

September 2020 – February 2021



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



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

# Content

01. Interim Report Q2 .....	3
02. NextCell Pharma .....	4
03. CEO comments .....	5
04. Product Portfolio .....	6
05. ProTrans™ .....	7
06. Clinical trials with ProTrans™ stem cells .....	8
07. Cellaviva - from birth to life .....	11
08. Development in numbers during the period.....	12
09. Income statement.....	14
10. Balance sheet .....	15
11. Cash flow statement .....	17
12. Statement of changes in equity .....	18



# 01.

## Interim Report Q2

"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.



### Second quarter (2020-12-01 until 2021-02-28)

- Operating income amounted to SEK 1,007,846 (1,364,645).
- Operating result amounted to SEK -8,148,299 (-4,228,449).
- Earnings per share\* amounted to SEK -0.27 (-0.22).
- Cash and bank amounted to SEK 148,936,293 (10,700,725).
- Solidity\*\* amounted to 96.8 (80.2) percent.

### First six month (2020-09-01 until 2021-02-28)

- Operating income amounted to SEK 2 140 858 (2 586 733).
- Operating result amounted to SEK -13 621 085 (-7 970 016).
- Earnings per share\* amounted to SEK -0,51 (-0,42).

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

- A prospectus was published at the beginning of December and a subscription period began following the fully guaranteed rights issue of SEK 150 million, decided by the Board on November 26, 2020, with the support of authorization from the Annual General Meeting on 24 November 2020.
- In early December, NextCell published results from the clinical trial ProTrans-Repeat. The primary endpoint, safety, has been 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 announced in mid-December 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 announced the outcome in the rights issue. The issue was oversubscribed and thus, NextCell has been 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.

### Significant events after the reporting period

- NextCell announced in the beginning of March, the decision to build a production facility in order to optimize and further scale up for a future market approval. NextCell has an agreement with the landlord Hemsö and the clean room supplier QleanAir to build a production facility in direct connection to the Company's existing office and clean room in the Novum building at Karolinska University Hospital in Huddinge. The construction will take place during the spring 2021 and the premises are expected to be completed in the third quarter of 2021. The expansion of the existing NextCell production capacity with an internal GMP facility is a further development of the ProTrans manufacturing process, from 2-dimensional cell culture to 3-dimensional bioreactor, in accordance with the awarded Eurostars Horizon 2020 grant of SEK 5 million. The primary purpose of NextCell's GMP facility is to prepare technology transfer to a potential partner or additional contract manufacturer in addition to the PBKM FamiCord Group.
- The Board of NextCell decided, with the support of the authorization by Annual General Meeting's on November 24, 2020, on a directed issue of 666,666 shares to Consensus Sverige Select. The subscription price was set at SEK 15 per new share, and the Company received approximately SEK 10 million. The purpose of the issue of shares, and the reason for the deviation from the shareholders' preferential rights is to broaden the shareholder base and to finance the Company's investment in its own production facility as communicated by a press release on 2 March 2021.
- NextCell announced in mid-April, that the Academic Hospital and Chief Examiner Professor Per-Ola Carlsson have been granted approval from the Medical Products Agency and the Swedish Ethical Review Authority to conduct a pediatric clinical drug trial with ProTrans to treat children and adolescents with type 1 diabetes. The study is a phase I/II study with a total of 66 patients. The first six patients, three adolescents (12-18 years) and then three children (7-11 years), will be evaluated for safety. Thereafter, a randomized, placebo-controlled part is performed to evaluate the treatment effect.

\*Result per share: operating results divided by the average number of shares. Average number of shares for the second quarter of 2020/2021 is: 29,717,519 (19,144,092) shares and the average number of shares for the first six months of 2020/2021 is: 26,540,470 (19,144,092). Number of shares in NextCell as per February 28th, 2021 is: 33,712,857 (19,144,092) shares.

\*\* Solidity/Equity ratio: shareholders' equity of the balance sheet total.

# 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.

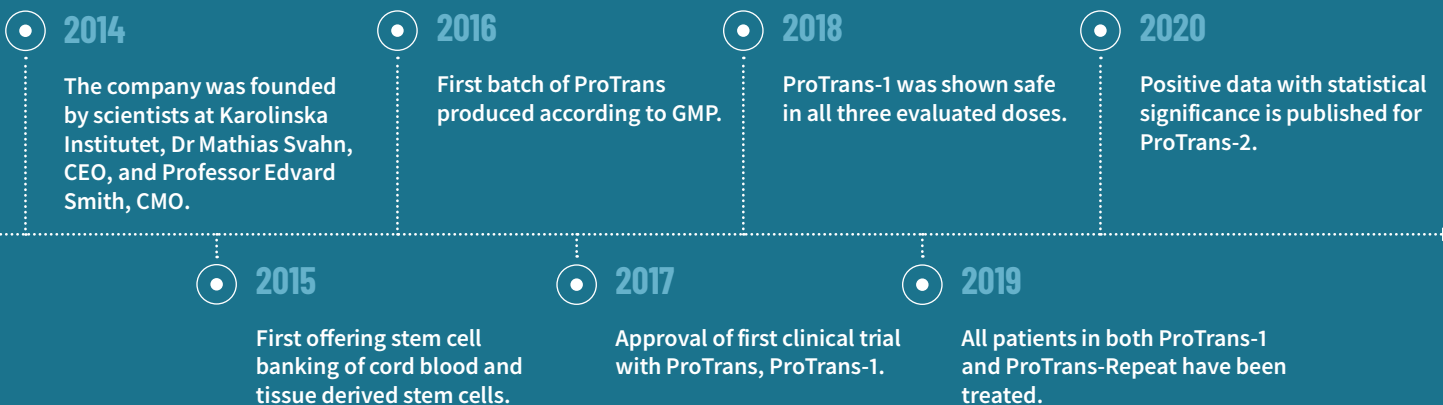
NextCell was founded in 2014 by researchers at Karolinska Institutet, initially under the name Cellaviva AB. NextCell's business concept is to develop and commercialize stem/stromal cell therapies based on the Company's novel selection algorithm (patent pending). Beside generating stromal cell therapies, 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 newborn 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 Company's goals is for ProTrans to become the first treatment targeting the underlying disease in type 1 diabetes.**

### Company history



# 03.

## CEO comments

During the second quarter of our fiscal year, NextCell has made progress on several fronts.

### In the financial area:

An oversubscribed rights issue of SEK 150 million, oversubscribed; a directed issue of approximately SEK 4 million to NextCell's most important partner, PBKM; and most recently after the end of the period, a directed issue of SEK 10 million to Consensus Sverige Select, granted with the award Best Sweden Fund 2020. The money will primarily be used to bring ProTrans to market via a phase-3 study, conduct other trials of ProTrans in diabetes and other indications, and build our own production facility.

### In the Diabetes area:

During the past quarter data from ProTrans-Repeat, a study where patients with type 1 diabetes are treated with a second dose of ProTrans, were presented. It is a small study but of great importance with safety as primary endpoint after receiving a repeated treatment of ProTrans. No serious side effects or other problematic effects were found. Thus, ProTrans can be given at more than one occasion while maintaining safety, a finding that opens the opportunity to develop treatment strategies over time. The trend is clear as two out of three patients had increased insulin production after 24 months compared with before the first treatment with ProTrans.

After the period ended, we also announced that Uppsala University has received approval from both the Medical Products Agency and the Swedish Ethical Review Authority to treat 66 young people and children who recently have developed diabetes. I am proud and grateful that Per-Ola Carlsson, together with Johnny Ludvigsson and Helena Elding Larsson, will run this important study and NextCell is pleased to contribute with ProTrans and Placebo.

Our main focus right now is to get the phase-3 study started. Market approval for ProTrans for the treatment of type-1 diabetes can be achieved most quickly by conducting a phase-3 study similar to the ProTrans-2 study. This phase-3 study will align with the Protrans-2 study in terms of treatment regimen and patient population i.e., treating patients between 18-40 years with a dose of ProTrans. We are now in discussions with the European Medicines Agency, EMA regarding the phase-3 study.

### In the Covid-19 area:

ProTrans is an immunomodulatory therapy, a platform technology with the potential to treat autoimmune diseases and inflammatory conditions. Mesenchymal stem cells are balancing the body's immune system between inflammation and allowing regeneration. On some occasions, the balance is disturbed due to genetics, infections or other external factors that require a large dose of mesenchymal stem cells to restore balance. A current example is in severe pneumonia due to SARS-CoV-2 infection. Covid-19 is an acute viral disease, and in the



worst cases, can lead to a stage where the body's immune system becomes hyperactivated and destroys itself. The aim is to investigate whether a dose of ProTrans can protect the patient from ending up on a respirator and require long rehabilitation. At best, this therapy could be lifesaving. It is also a valuable opportunity for NextCell to gain experience in the treatment of diseases other than diabetes in order to broaden our knowledge.

McGill University in Montreal has been granted an accelerated approval from Health Canada to conduct a phase-2 study with ProTrans for the treatment of hyperinflammation of the lungs caused by the coronavirus. The regulatory process has been shortened to meet an urgent need. NextCell has established a close collaboration with doctors and researchers, something we can benefit from in the future.

In parallel with the Canadian study, a dose-escalation trial with Covid patients is underway in Örebro. We see value in conducting another dose escalation study as there are great fundamental differences between diabetes and Covid. ProTrans is given intravenously into the armpit and a large part of the cells are expected to get caught in the small blood vessels in the lung, which is optimal as the virus specifically causes hyperinflammation in the lungs.

### In the Cellaviva area:

In March, family savings of stem cells from umbilical cord and cord blood for possible future use have, following a period of stagnant sales, reached previous sales records. This has happened despite complicated circumstances with visitation restrictions at the hospitals and uncertainty in the household finances. Increased evidence for family savings of stem cells in combination with enhanced exposure is reflected in sales statistics and will also, with a certain delay, be seen in the company's future results.

The second quarter of NextCell's fiscal year has shown strength and growth on several fronts. I would like to thank all loyal employees and shareholders and, at the same time, welcome all new ones. We work passionately to drive the company forward and hope to show continued progress during this current third quarter.

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



# 04.

## Product Portfolio

NextCell's product portfolio is based on mesenchymal stem cells from Wharton's Jelly (WJMSCs), ie the jelly 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™ (Pro-

Trans). 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 Algorithm 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 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 amount 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 patients 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.

### **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. Patienterna som ingått i studierna är alla mellan 18-40 år, har diagnostiserats med diabetes typ-1 under de senaste två-tre åren och bibehåller fortfarande viss egen insulinproduktion. De kliniska prövningarna har utförts av Karolinska Trial Alliance, under ledning av professor Per-Ola Carlsson, Uppsala universitet, huvudprövare. Säkerhetskommittén utgörs av Professorerna Ulf Smith och Anders Fasth vid Göteborgs universitet samt Åke Lernmark vid Lunds universitet.

#### ProTrans-1

ProTrans-1 was started in January 2018 as a phase I study, evaluating ProTrans™ (ProTrans) safety and its 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 efficacy as 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-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 additional 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 Young

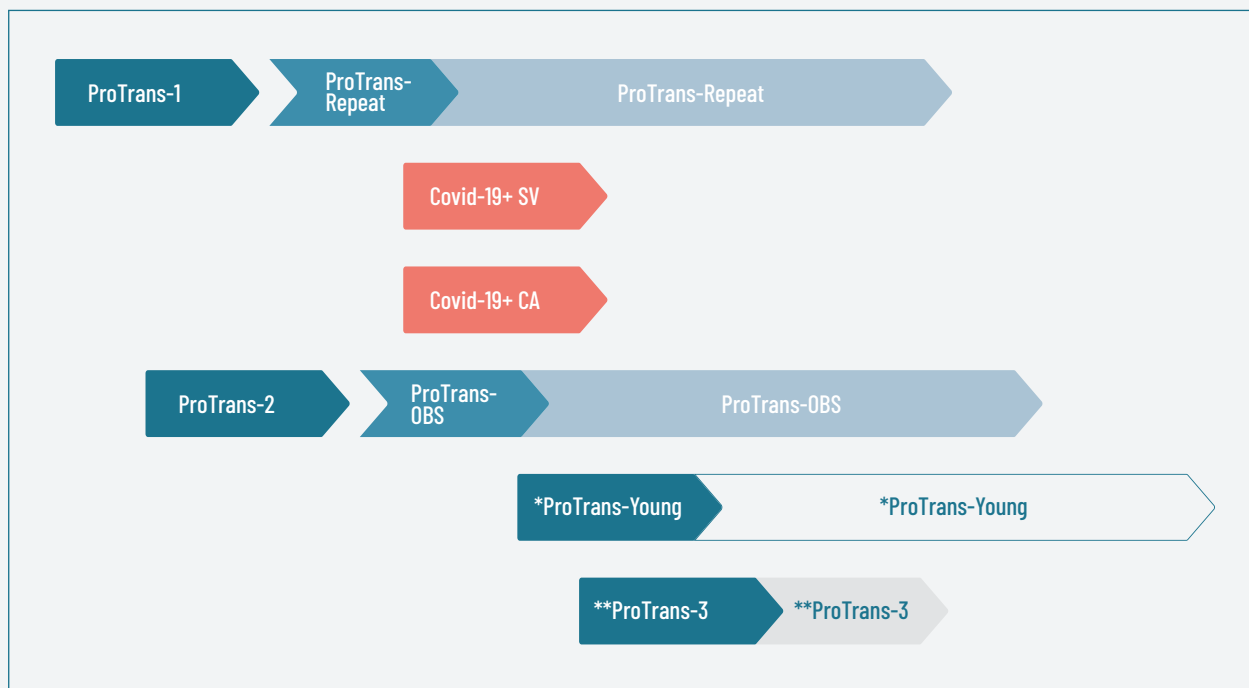
ProTrans-Young is a pediatric ProTrans study for the treatment of children and adolescents with type 1 diabetes. The trial is initiated by, and will also be carried out by Professor Per-Ola Carlsson, principal investigator for all NextCell's diabetes studies, together with the co-investigators Professor Helena Elding Larsson, Skåne University Hospital and Professor Johnny Ludvigsson, Linköping University Hospital. Sponsor is Uppsala Universitet, NextCell will contribute ProTrans and Placebo to the study. The study has received approval from the Medical Products Agency and the Swedish Ethical Review Authority and start is expected to the third quarter of 2021. ProTrans Young is a phase I / II study with a total of 66 patients. The first six patients treated will be evaluated for safety. The first six patients, three adolescents (12-18 years) and three children (7-11 years), will be treated and assessed for safety. After that, a randomized, placebo-controlled phase will be performed to evaluate the treatment efficacy.

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

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. In addition, McGill University in Montreal has been granted with a approval from Health Canada to conduct a phase-2 study with ProTrans for the treatment of hyperinflammation of the lungs caused by the coronavirus. The study is sponsored by the Research Institute of the McGill University Health Center and NextCell contributes with study drugs. The study will include 48 patients with severe pneumonia and confirmed Covid-19 where 24 patients are randomized to ProTrans treatment and another 24 patients will receive placebo.

### Clinical Trials

Follow up periods in pale



*\*ProTrans Young is an investigator initiated trial, sponsored by Uppsala University Hospital.*

*\*\*ProTrans-3 is not yet approved.*

## 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 the development of new therapies for autoimmune and inflammatory diseases, 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 umbilical 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.

**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.



\* [www.clinicaltrials.com](http://www.clinicaltrials.com)

# 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 second quarter of 2020/2021 amounts to SEK 1.0 (1.4) million, where SEK 1.0 (1.3) million relates to income from Cellaviva's operations. This means, revenues decreased by SEK 0.3 million, corresponding to -23 percent between the periods. Revenues related to Cellaviva have shown steady growth over the past two years. However, during the past six months a slowdown has been noted which can be explained by the current pandemic. The restrictions with restraining orders on the deliveries makes it difficult for our midwives to accomplish some of the planned stem cell collections. We have also noticed that the economic crisis, as a result of the pandemic, leads to potential customers refraining from investing in stem cell savings. In recent months, however, we see that sales have turned up again in both Sweden and Denmark, which is expected to have an impact on revenue in the coming quarters.

### Financial development

The result for the first quarter 2020/2021 amounts to SEK -8.1 (-4.2) million and the total cost base for the period amounts to SEK -9.2 (-5.5) million, which means an increase of SEK 3.7 million (67 percent). The increase is in line with the budget and is mainly traced to the item Other external costs and Personnel 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 February 28, 2021 amounted to SEK 148.9 (10.7) million. Total cash flow for the second quarter 2020/2021 amounted to SEK 132.1 (5.0) million. During the period, in December 2020, a rights issue was carried out which provided the Company with SEK 150.0 million, approximately SEK 134.5 million after deductions for transaction costs. In addition, in January 2021, a directed issue was carried out which provided the company with SEK 4.3 million, approximately SEK 4.2 million after deductions of transaction

costs. Cash flow from operating activities amounted to SEK 6.9 (4.2) million. Thus, cash flow from operating activities has increased by SEK 2.7 million, corresponding to 64% which is in line with expectations and budget as the business gradually is scaling up due to the planned Phase III study. The cash flow for the first six months amounted to SEK 127.0 (-9.4) million, of which the cash flow from operating activities amounts to SEK -12.2 (-8.6) million. After the end of the period, in March 2021, a directed issue was carried out which provided the Company with SEK 10.0 million, approximately SEK 9.4 million after deduction of transaction costs. The Company assesses that it has financing to run the business with the planned scope of activities, including the Phase III study, for at least three years ahead.

### Solidity

The solidity ratio as per February 28, 2021 amounted to 96.8 (80.2) %.

### 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". During the second quarter of 2020/2021, two issues were carried out. 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. In January 2021, a direct issue was carried out, which meant that the share capital increased by SEK 58,766.53 through the issue of 286 666 shares. As of February 28, 2021, after registration of the two issues, the number of shares amounted to 33,712,857 and the share capital to SEK 6,911,135.685. The average number of shares during the second quarter was 29,717,519 (19,144,092). All shares are of the same type and denominated in Swedish kronor (SEK).

As of February 28, 2021, the number of shareholders was approximately 5,170 (2,830). The ten largest owners held shares corresponding to 46.8 percent of the total number.

The list below shows the ten largest shareholders in NextCell Pharma as per 2021-02-28

NAME	SHARES	VOTES AND CAPITAL (%)
Diamyd Medical AB	4,283,861	12.71
Avanza Pension	3,827,312	11.35
Anders Essen-Möller*	2,518,909	7.48
Ålandsbanken	1,177,287	3.49
Pabros AB	847,452	2.51
Christer Jansson	784,844	2.33
Nordnet Pensionsförsäkring	666,674	1.98
Konstruktions och försäljningsaktiebolaget	650,000	1.93
Robert Joki	532,742	1.58
BioAll**	494,599	1.46
<b>Total</b>	<b>15,783,680</b>	<b>46.82</b>

\*In addition to Chairman of the Board, Anders Essen-Möller's directly registered holdings, this item includes holdings of 4.17 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 0.20 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.

### Certified Adviser

For companies listed on Nasdaq First North Growth Market, a certified adviser is required. Certified Adviser for NextCell is FNCA Sweden AB, 08-528 00 399, info@fnca.se.

### Financial calendar

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

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

### Publication of interim report

Huddinge, April 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



# Income statement

(SEK)	2020-12-01 2021-02-28	2019-12-01 2020-02-29	2020-09-01 2021-02-28	2019-09-01 2020-02-29	2019-09-01 2020-08-31
<b>Operating income</b>					
Net income	1,007,846	1,331,590	1,828,740	2,469,178	3,564,701
Other operating income	0	33,055	312,118	117,555	601,422
<b>Total operating income</b>	<b>1,007,846</b>	<b>1,364,645</b>	<b>2,140,858</b>	<b>2,586,733</b>	<b>4,166,123</b>
<b>Operating expense</b>					
Materials and goods	-4,014,184	-1,846,465	-6,118,057	-3,617,705	-6,765,340
Other external costs	-2,032,049	-1,692,114	-4,138,088	-3,067,767	-7,172,686
Personnel costs	-3,065,086	-1,977,665	-5,365,867	-3,713,893	-7,506,910
Depreciation	-101,574	-92,742	-196,679	-172,364	-397,102
Other operating expenses	0	0	0	0	-26,453
<b>Total operating expenses</b>	<b>-9,212,893</b>	<b>-5,608,986</b>	<b>-15,808,692</b>	<b>-10,571,729</b>	<b>-21,868,490</b>
<b>Operating results</b>	<b>-8,205,047</b>	<b>-4,244,341</b>	<b>-13,677,833</b>	<b>-7,984,996</b>	<b>-17,702,367</b>
<b>Financial income and expenses</b>					
<i>Interest received</i>	56,994	16,167	56,994	16,167	30,508
<i>Interest expenses and similar expenses</i>	-246	-275	-246	-1,187	-8,838
<b>Total</b>	<b>-56,748</b>	<b>15,892</b>	<b>56,748</b>	<b>14,980</b>	<b>21,670</b>
<b>Result before taxes</b>	<b>-8,148,299</b>	<b>-4,228,449</b>	<b>-13,621,085</b>	<b>-7,970,016</b>	<b>-17,680,697</b>
<b>Taxes</b>					
Tax expenses for the period	0	0	0	0	0
<b>Net result for the period</b>	<b>-8,148,299</b>	<b>-4,228,449</b>	<b>-13,621,085</b>	<b>-7,970,016</b>	<b>-17,680,697</b>

# 10.

## Balance sheet

(SEK)	2021-02-28	2020-02-29	2020-08-31
<b>ASSETS</b>			
<b>Non current assets</b>			
<i>Tangible non-current assets</i>			
Property, plant and equipment	1,547,685	1,483,200	1,340,186
Inventories, tools and installations	1,227,148	1,607,187	1,274,346
	<b>2,774,833</b>	<b>3,090,387</b>	<b>2,614,532</b>
<i>Financial assets</i>			
Other long-term receivables	1,129,193	1,128,193	1,128,193
	<b>1,129,193</b>	<b>1,128,193</b>	<b>1,128,193</b>
<b>Total non-current assets</b>	<b>3,904,026</b>	<b>4,218,580</b>	<b>3,742,725</b>
<b>Current assets</b>			
<i>Current receivables</i>			
Trade receivables	974,308	971,085	820,235
Other receivables	244,956	470,290	454,011
Prepaid expenses and accrued income	2,850,527	2,331,847	2,798,783
	<b>4,069,791</b>	<b>3,773,222</b>	<b>4,073,028</b>
<b>Liquid assets</b>	<b>148,936,293</b>	<b>10,700,725</b>	<b>21,958,336</b>
<b>Total current assets</b>	<b>153,006,083</b>	<b>14,473,947</b>	<b>26,031,364</b>
<b>TOTAL ASSETS</b>	<b>156,910,109</b>	<b>18,692,527</b>	<b>29,774,089</b>

## Balance sheet cont.

(SEK)	2021-02-28	2020-02-29	2020-08-31
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<i>Restricted equity</i>			
Share capital	6,911,136	3,924,539	4,796,658
<i>Non-restricted equity</i>			
Profit or loss brought forward	-28,827,505	-644,003	-14,599,803
Shareholders surplus	187,450,896	19,679,793	53,702,295
Result for the period	-13,621,085	-7,970,016	17,680,697
	<b>145,002,305</b>	<b>11,065,773</b>	<b>21,421,795</b>
<b>Total equity</b>	<b>151,913,441</b>	<b>14,990,312</b>	<b>26,218,453</b>
<b>Liabilities</b>			
<i>Long-term liabilities</i>			
Other long-term liabilities	1,621,890	944,499	1,380,802
<i>Current liability</i>			
Trade payable	1,245,752	1,562,371	477,603
Other liabilities	359,297	243,083	176,569
Prepaid income accrued expenses	1,769,728	952,261	1,520,662
	<b>3,374,778</b>	<b>2,757,715</b>	<b>2,174,834</b>
<b>Total liabilities</b>	<b>4,996,668</b>	<b>3,702,215</b>	<b>3,555,636</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>156,910,109</b>	<b>18,692,527</b>	<b>29,774,089</b>

## Cash flow statement

(SEK)	2020-12-01 2021-02-28	2020-12-01 2020-02-29	2020-09-01 2021-02-28	2019-09-01 2020-02-29	2019-09-01 2020-08-31
	3 MO	3 MO	6 MO	6 MO	12 MO
<b>Operating activities</b>					
Operating profit/loss	-8,205,047	-4,244,341	-13,677,833	-7,984,996	-17,702,367
<b>Non-cash flow items</b>					
Depreciation	101,574	92,742	196,679	172,364	397,102
Revenue from disposal of assets	0	0	0	16,167	-28,883
Interest received	56,994	16,167	56,994	-1,187	30,508
Interest paid	-246	-275	-246		-8,838
<b>Cashflow from operating activities before changes in working capital</b>	<b>-8,046,725</b>	<b>-4,135,707</b>	<b>-13,424,406</b>	<b>-7,797,652</b>	<b>-17,312,478</b>
<b>Changes in working capital</b>					
Increase / decrease in receivables	-126,098	-307,186	3,237	-704,741	-1,004,547
Increase / decrease in payables	721,330	190,682	768,149	140,536	-944,231
Increase / decrease in other short-term payables	536,805	16,424	431,794	-200,504	301,384
<b>Total of working capital</b>	<b>1,132,037</b>	<b>-100,080</b>	<b>1,203,180</b>	<b>-764,708</b>	<b>-1,647,394</b>
<b>Net cash flow from operating activities</b>	<b>-6,914,688</b>	<b>-4,235,787</b>	<b>-12,221,226</b>	<b>-8,562,360</b>	<b>-18,959,872</b>
<b>Investing activities</b>					
Investments in material and immaterial assets	-324,996	-787,113	-356,980	-787,113	-787,113
Sale of fixed assets					280,000
Investments in financial assets	0	0	-1,000	-82,900	-82,900
<b>Net cash flow from investing activities</b>	<b>-324,996</b>	<b>-787,113</b>	<b>-357,980</b>	<b>-870,013</b>	<b>-590,013</b>
<b>Financing activities</b>					
Long-term liabilities	49,696	8,207	241,088	4,913	441,216
New issue	154,717,845	0	154,717,845		25,100,028
Cost related to the new issue	-15,401,772	0	-15,401,772		-4,161,206
<b>Net cash flow from financing activities</b>	<b>139,365,769</b>	<b>8,207</b>	<b>139,316,073</b>	<b>4,913</b>	<b>21,380,038</b>
<b>Cash flow for the period</b>					
Cash and cash equivalents at beginning of period	16,810,206	15,715,418	21,958,336	20,128,185	20,128,185
Change in cash and cash equivalents	132,126,085	-5,014,693	126,977,956	-9,427,460	-1,830,151
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>148,936,293</b>	<b>10,700,725</b>	<b>148,936,293</b>	<b>10,700,725</b>	<b>21,958,336</b>

# 12.

## Statement of changes in equity

2020-08-31

	SHARE CAPITAL	BALANCED RESULT	SHARE PREMIUMS	NET RESULT OF THE PERIOD	TOTAL EQUITY
<b>Opening balance 2019-09-01</b>	<b>3,924,539</b>	<b>6,850,981</b>	<b>30,182,598</b>	<b>-17,997,789</b>	<b>22,960,329</b>
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
<b>Closing balance 2020-08-31</b>	<b>4,796,658</b>	<b>-11,146,808</b>	<b>50,249,300</b>	<b>-17,680,697</b>	<b>26,218,453</b>

2021-02-28

	SHARE CAPITAL	BALANCED RESULT	SHARE PREMIUMS	NET RESULT OF THE PERIOD	TOTAL EQUITY
<b>Opening balance 2020-09-01</b>	<b>4,796,658</b>	<b>-11,146,808</b>	<b>50,249,300</b>	<b>-17,680,697</b>	<b>26,218,453</b>
Disposition from AGM		-17,680,697		17,680,697	0
New issue	2,114,477		152,603,368		154,717,845
Cost related to the new issue			-15,401,772		-15,401,772
Result				-13,621,085	-13,621,085
<b>Closing balance 2020-11-30</b>	<b>6,911,136</b>	<b>-28,827,505</b>	<b>187,450,896</b>	<b>-13,621,085</b>	<b>151,913,441</b>





## 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](http://www.nextcellpharma.com) | [www.cellaviva.se](http://www.cellaviva.se)