# REPLICEL LIFE SCIENCES INC. MANAGEMENT DISCUSSION AND ANALYSIS FORM 51-102F1

# For the period ended March 31, 2021

# Dated as of May 31, 2021

The following management discussion and analysis ("MD&A") of the financial position, results of operations and cash flows of RepliCel Life Sciences Inc. (the "Company" or "RepliCel"), for the three months ended March 31, 2021 includes information up to and including May 31, 2021 and should be read in conjunction with the annual audited consolidated financial statements for the years ended December 31, 2020, 2019, and 2018 and the condensed consolidated interim financial statements for the three months ended March 31, 2021.

The financial statements of the Company for the three months ended March 31, 2021 have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

All amounts included in the consolidated financial statements and MD&A are expressed in Canadian dollars unless otherwise indicated. The reader is encouraged to review the Company's filings on the SEDAR website at www.sedar.com.

#### **Cautionary Statement Regarding Forward-Looking Statements**

Statements included in this MD&A that do not relate to present or historical conditions are "forward-looking statements". Forward-looking statements are projections in respect of future events or the Company's future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may", "should", "intend", "expect", "plan", "anticipate", "believe", "estimate", "predict", "potential", or "continue", or the negative of these terms or other comparable terminology. Forward-looking information presented in such statements or disclosures may, among other things, include the Company's:

- belief that chronic tendon injuries resulting from sports-related or occupational overuse is a significant unmet medical need:
- belief that RCT-01 has advantages over current treatments such as the use of non-steroidal anti- inflammatory medication or corticosteroids which are limited in efficacy;
- belief that the data from a phase 1/2 clinical trial to test the safety and efficacy of injections of RCT-01 on patients suffering from chronic achilles tendinosis in Canada are sufficient to support regulatory approvals to proceed to a phase 2 trial and the design of such a dose-finding trial;
- belief that the data from the phase 1 clinical trial to test the safety and certain biological outcomes of injections of RCS-01 in patients with aging and sun-damaged skin supports regulatory approvals to proceed to a phase 2 trial and the design of such a dose-finding trial;
- research pertaining to and plan to continue to prepare for a phase 2 dose-finding trail for RCH-01 and details of such a trial;
- belief that the RCI-02 dermal injector device will have applications in certain dermatological procedures and
  preparation for its commercialization including building of commercial/clinical-grade prototypes, validation
  testing of such prototypes, filing of the regulatory submissions seeking regulatory approval to market the
  device will lead to commercial launch, revenue generation, and commercial partners; expectations regarding
  regulatory clearances to conduct trials and market products;
- belief that it will be able to meet the requirements to conduct clinical research studies of RCT-01 and RCS-01 in Japan under the guidelines of Japan's Act for the Safety of Regenerative Medicine (ASRM) regulations using its current contract manufacturing facility, Innovacell in Innsbruck, Austria, and that positive safety and clinical data from such studies could be sufficient to support the Company's commercial launch of both products in Japan;
- belief as to the potential of the Company's products;
- expectations regarding the performance of its commercial partners, YOFOTO, Shiseido, and MainPointe;

- expectations regarding the payment of milestone payments by YOFOTO;
- expectations regarding the ability of the Company to procure new partnerships in Japan to fund clinical development/testing of RCS-01 and RCT-01 products in Japan;
- expectations regarding the performance of critical suppliers and service providers;
- forecasts of expenditures;
- expectations regarding our ability to raise capital;
- business outlook;
- plans and objectives of management for future operations; and
- anticipated financial performance.

Various assumptions or factors are typically applied in drawing conclusions or making the forecasts or projections set out in forward-looking information. Those assumptions and factors are based on information currently available to the Company, including information obtained from third-party industry analysts and other third party sources. In some instances, material assumptions and factors are presented or discussed elsewhere in this MD&A in connection with the statements or disclosure containing the forward-looking information. You are cautioned that the following list of material factors and assumptions is not exhaustive. The factors and assumptions include, but are not limited to, our assumption that there be:

- no unforeseen changes in the legislative and operating framework for the business of the Company;
- a stable competitive environment; and
- no significant event occurring outside the ordinary course of business such as a natural disaster or other calamity.

These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks set out in the section entitled "Risks and Uncertainties" commencing on page 19, which may cause the Company's or its industry's actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to the following risks:

- negative results from the Company's clinical studies and/or trials;
- the effects of government regulation on the Company's business;
- the viability and marketability of the Company's technologies;
- the development of superior technology by the Company's competitors;
- the failure of consumers and the medical community to accept the Company's technology as safe and
  effective:
- risks associated with the performance of commercial partners, critical suppliers and service providers;
- risks associated with disagreements or disputes with the Company's commercial partners, critical suppliers, and service providers;
- risks associated with the Company's ability to obtain and protect rights to its intellectual property;
- risks and uncertainties associated with the Company's ability to raise additional capital;
- risks and uncertainties associated with shutdowns or delays caused by the COVID-19 pandemic; and
- other factors beyond the Company's control.

Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company cannot guarantee future results, levels of activity or performance. Further, any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by applicable law, the Company undertakes no obligation to update any forward-looking statement to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for management to predict all of such factors and to assess in advance the impact of such factors on the Company's business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statement.

#### **OVERALL PERFORMANCE**

The Company was incorporated under the Ontario *Business Corporations Act* on April 24, 1967. The Company is a foreign private issuer in the United States. The Company's common shares are listed for trading in Canada on the TSX Venture Exchange, trading under the symbol "RP", in the United States on the OTCPK, trading under the symbol REPCF, and in Germany on the Frankfurt Stock Exchange (FRA) under the symbol P6P2.

RepliCel is a regenerative medicine company focused on developing autologous cell therapies that treat functional cellular deficits. The diseases currently being addressed are chronic tendinosis, skin aging, and androgenetic alopecia (pattern baldness). Each disease state is consistent with a deficit of a specific cell type which the Company believes is critical to normal function. All treatments under development are based on RepliCel's innovative technology which utilizes cells isolated from a patient's own healthy hair follicles. These products are built on the Company's proprietary manufacturing platforms and are covered by issued and filed patents, as well as trade secrets. RepliCel is also developing a programmable injector device and related consumables designed for dermal injections of cells as currently approved other products such as dermal fillers, toxins, enzymes, drugs, and biologics such as fat transfer, platelet rich plasma, antibodies, etc.

# The Potential of Autologous Cell Therapy

The Company's treatments use autologous cell therapy ("ACT"), which is one of the most rapidly developing areas of regenerative medicine in the development of novel treatments for numerous human disorders. ACT involves isolating an individual's own cells from harvested tissues and growing more of those cells, or 'expanding' those cells, in controlled conditions in a laboratory. These purified, expanded cells are then reintroduced to the donor to treat a specific condition. The benefits of autologous (derived from the same person) therapy (as compared to allogeneic derived from a different person) includes minimized risks of systemic immunological (anaphylactic) reactions, bioincompatibility, and disease transmission. Furthermore, the effects of ACT may be more curative, regenerative, and/or longer lasting than other topical, biologic, pharmacological or surgical interventions.

The Company has an extensive intellectual property portfolio that covers RCT-01 (our platform for tendon repair); RCS-01 (our platform for skin rejuvenation); RCH-01 (our platform for pattern baldness); and RCI-02 (our dermal injection device and consumables). Our intellectual property portfolio includes both patents and patent applications which we have developed and own (discussed in more detail below).

# RCT-01: Treatment for Chronic Tendinosis

# **Background**

Tendinosis refers to a chronic disease of the tendon. It is a function of an imbalance of tendon breakdown and tendon repair initiated first by an injury which does not heal properly. This leads to cycles of compromised repair and subsequent re-injury until such time as there is no healing and a degenerative process has set in. Typically, this chronic condition is linked to aging, overuse, and to general health. The Company believes that the current standard of care is failing to provide a satisfactory solution to this chronic condition.

# **Treatment**

The Company believes that chronic tendon injuries resulting from sports-related or occupational overuse is a significant unmet medical need. Tendons consist of specialized connective tissues that attach muscles to bones, transmitting force and supporting the musculoskeletal system. When mechanical loads exceed the strength of a tendon or tensile range is lost due to aging, micro-tears of the collagen fibers within tendon occur. Once a tendon is injured, healing can occur intrinsically via tenocyte activation within the injured site or extrinsically via recruitment of collagen-producing cells from the surrounding area. Naturally healed tendon does not return to the same physiological state as 'intact' tendon, even when it supports a return to normal function. Inadequate rest and improper healing often result in re-injury and rupture.

Current treatments manage pain and facilitate healing processes; however, they do not mediate complete recovery and leave patients demobilized for several months during treatment. The Company believes that improved therapeutic strategies are therefore in considerable demand. The Company's fibroblast technology for tendinosis, which the Company refers to as RCT-01, has been developed over five years of research, experimentation and trials. RCT-01 is a tissue-engineered product made from a procedure using collagen-producing fibroblasts isolated from non-bulbar dermal sheath (NBDS) cells within the hair follicle that are replicated in culture. These fibroblasts are efficient producers of type I collagen and because they are of anagen hair follicle mesenchymal origin, they have the potential to replicate efficiently in culture. The use of these fibroblasts are, therefore, ideal for treating chronic tendon disorders that arise due to either a degeneration of collagen producing cells or a deficit of active collagen producing cells. Because RCT-01 directly provides a source of collagen expressing cells to the site of injury, addressing the underlying cause of tendinosis, the Company believes it has advantages over current treatments such as the use of non-steroidal anti-inflammatory medication or corticosteroids which are limited in efficacy. Another advantage of RCT-01 is the autologous nature of the cellular product, thereby reducing the likelihood of adverse immune reactions upon administration.

#### Pilot Clinical Trials

Phase 1 human pilot clinical trials were conducted by the Company's collaborative partner, Dr. David Connell, which focused on tendinosis of the Achilles, patellar and lateral elbow (commonly referred to as tennis elbow) using skin tissue derived fibroblasts. In these trials, where 90 patients were injected with cultured, autologous fibroblasts, no adverse events were reported. The Company has expanded on Dr. Connell's approach by isolating NBDS fibroblasts from the hair follicle that express upwards of five times the amount of type I collagen than fibroblasts derived from skin tissue as pursued by Dr. Connell.

# Phase 1 Clinical Trial

On December 1, 2014, the Company announced receipt of a "No Objection Letter" from Health Canada in response to its Clinical Trial Application to Health Canada for its phase 1/2 clinical trial to test the safety and efficacy of injections of RCT-01 on patients suffering from chronic Achilles tendinosis. Health Canada's clearance to initiate the trial permitted the participation of subjects who have failed traditional tendon treatments and who are otherwise in good health. Trial design was randomized, double-blinded, placebo-controlled with a treatment-to-placebo ration of 3:1. The mechanics of the Company's treatment involve the extraction of as few as 20 hair follicles from the back of a patient's scalp via a single punch biopsy. NBDS cells are isolated from the hair follicle sheath, replicated in a current Good Manufacturing Practices (cGMP) facility and are then reintroduced under ultrasound guidance directly into the area of damaged tendon. The collagen rich fibroblast cells are expected to initiate and complete the healing of the chronically injured tendon. After injections are performed, subjects will return to the clinic for assessments of safety, function and pain, as well as changes in tendon thickness, echotexture, interstitial tears and neovascularity.

This trial commenced in 2015 and final data was announced Q1 2017. The primary end point of safety was met while secondary end points related to efficacy were also measured at nine-months post-injection of RCT-01. The Company may pursue further indications of other tendon populations including patellar tendinosis (jumper's knee) and lateral and medial epicondylitis (tennis and golfer's elbow).

#### Further Clinical Trials

The Company is now designing further clinical testing intended to measure efficacy of RCT-01 in patients with chronic tendinosis. The Company is currently engaged in a dual-track plan to commercialize RCT-01 in Japan as quickly as possible. Firstly, the Company is preparing for a university-sponsored clinical research study of RCT-01 in patients with tendinopathy under that country's ASRM regulations. Successful safety and efficacy data from such a study can be sufficient to support market launch of a product albeit without reimbursement or formal PMDA approval. Secondly, RepliCel has successfully completed the second of three consultations required to obtain clearance from Japan's regulatory agency (the Pharmaceutical and Medical Devices Agency, PMDA) to proceed with a clinical trial of RCT-01 under the PMD Act. This pathway leads to formal PMDA approval and reimbursement. Successful data from such a trial could lead to 'conditional approval' for market launch of RCT-01 in Japan with reimbursement pending data from a larger pivotal trial leading to full non-conditional approval.

In addition to RepliCel's intended conduct of a clinical trial in Japan, RepliCel's partner, YOFOTO (see below), is expected to conduct a clinical trial of RCT-01 in China. This trial is anticipated to be a phase 2 trial designed to answer critical questions related to dosing and treatment frequency.

# Collaboration Agreement

The Company has a Collaboration and Technology Transfer Agreement with YOFOTO (China) Health Industry Co. Ltd. ("YOFOTO"). RepliCel and YOFOTO are collaborating on a clinical research program in China, with the goal of increasing the available human clinical data on RCT-01. The Company anticipates that collaborative technology transfer will continue between the companies as any new improvements to the RCT-01 technology are developed by either party. This agreement gives YOFOTO an exclusive 15-year geographic license to develop and market the Company's RCT-01 tendon regeneration technology in Greater China (China, Hong Kong, Macau, and Taiwan).

#### **Intellectual Property**

The Company has filed patent applications worldwide relating to compositions, methods and uses of NBDS cells for the treatment and repair of tendons. Representative examples of this portfolio include patent applications filed in a variety of select jurisdictions such as Australia, Brazil, Canada, China, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, South Africa, the UAE and the United States (see e.g., US Pub No. 20150374757).

RCS-01: Treatment for Aging and Sun Damaged Skin

# Background

Skin is considered one of the most prominent indicators of one's age and health. Maintenance of healthy skin is dictated by intrinsic and extrinsic factors. While intrinsic factors (i.e. chronologic age, sex and genetic makeup) cannot be modified, the adverse effects caused by extrinsic factors such as UV radiation and smoking can be prevented or minimized by lifestyle modification. Although these extrinsic effects can be modulated, the extent to which they can be modified varies significantly among individuals, which largely depends on one's ability to detoxify and repair such damage.

The dermis and epidermis components of the skin lose thickness with age. Solar radiation, particularly UVA, is known to penetrate deep into the dermal layer, damaging fibroblasts, collagen and other fibroblasts expressed proteins, which are the major cellular components of the dermis. Similarly, there are some studies reporting that air pollutants/nanoparticles may also penetrate transepidermally, negatively impacting the dermal layer. The damages caused by external stimuli include DNA strand breaks and mutations, which, if not repaired properly, can lead to cell death. Similarly, oxidative stress caused by smoking leads to not only damages to DNA but also to other cellular components such as proteins and lipids.

Accumulation of damage to cellular proteins and DNA from years of exposure to extrinsic insults can lead to physiological changes of the skin that are irreversible. Such changes are often associated with a reduction in fibroblast cells, disorganization of collagen fibrils and decreased production of collagen, elastin and other glycoproteins that provide structural support and stability to the extra cellular matrix ("ECM") network. Such changes to the dermal components are detrimental to maintaining mechanical tensile ability and structural integrity of the skin.

# **Treatment**

The Company's NBDS-derived fibroblast therapy, which it refers to as RCS-01, provides a promising platform to treat intrinsically and extrinsically aged/damaged skin by providing UV-naïve collagen-producing fibroblast cells directly to the affected area. The Company's unique manufacturing technology allows for isolation of fibroblasts derived from anagen-hair follicle mesenchymal tissues, which elicit more efficient replication potential in culture. Additionally, the Company's proprietary culture procedures potentiate these cells to maintain plasticity, allowing the

cells to adapt to the microenvironment and respond to the mechanical or surrounding stimuli after injection, leading to robust production of type I collagen and elastin and their proper alignment within the tissue.

On September 1, 2015, the Company announced it had received clearance from the German Competent Authority, the Paul-Ehrlich-Institute, to initiate a Phase 1 clinical trial to investigate the potential safety and efficacy of injecting RCS-01 into subjects with aged or UV-damaged skin. This trial was a randomized, double-blind, placebo controlled study of intradermal injections of RCS-01 designed to assess local safety as well as systemic safety. This trial is now complete with data announced early April 2017 in which the primary endpoint, safety, was successfully established and secondary endpoints related to measurements of the impact on biomarkers related to skin-aging were significantly positive. A summary of the phase 1 clinical study data was published in the peer-reviewed journal, Skin Pharmacol Physiol.

#### **Further Clinical Trials**

The Company is now designing with its partner, YOFOTO (see below), further clinical testing of RCS-01 including a multi-centre phase 2 clinical trial intended to measure efficacy of RCS-01 in a larger population of patients with aging and UV-damaged skin and answer critical questions related to dosing and treatment frequency in China as well a clinical study in Japan.

The Company is currently engaged with the Japanese regulators in the reviews necessary to obtain regulatory clearance from the PMDA and Ministry of Health, Labour and Welfare (MHLW) to conduct its next clinical study of RCS-01 in Japan under the Act for the Safety of Regenerative Medicine (ASRM) with the intention of launching the product on the market in Japan after successful completion of such a trial. Other preparations required for the conduct of such a clinical study have also been initiated in Japan.

It is intended that all future clinical trials of RCS-01 will be conducted using prototypes of the RepliCel's RCI-02 dermal injector.

# **Collaboration Agreement**

The Company has a Collaboration and Technology Transfer Agreement with YOFOTO (China) Health Industry Co. Ltd. ("YOFOTO"). RepliCel and YOFOTO are collaborating on a clinical research program in China, with the goal of increasing the available human clinical data on RCS-01. The Company anticipates that collaborative technology transfer will continue between the companies as any new improvements to the RCS-01 technology are developed by either party. This agreement gives YOFOTO an exclusive 15-year geographic license to develop and market the Company's RCS-01 skin rejuvenation technology in Greater China (China, Hong Kong, Macau, and Taiwan).

#### **Intellectual Property**

The Company has filed patent applications relating to compositions, methods and uses of NBDS cells for the treatment and repair of aging and UV-damaged skin. Representative examples of this portfolio include patent applications filed in a variety of select jurisdictions such as Australia, Brazil, Canada, China, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Singapore, and the United States (see e.g., US Pub No. 20160136206).

#### RCH-01: Treatment for Hair Loss

# **Background**

Androgenetic alopecia (pattern hair loss) can affect up to 70% of men and 40% of women during the course of their lives. Although it is not a disease that causes physical pain, it does cause mental pain. Currently, over \$3 billion is spent each year on hair loss treatments that provide limited results. Androgenetic alopecia is largely an inherited disease. It can be inherited by males and females from either the mother's or father's side of the family. Women with this trait develop thinning hair, but do not commonly become completely bald.

Androgenetic alopecia is a process by which hair follicles shrink and produce smaller hairs thus reducing hair density. These miniaturized hair fibers have a shorter growth cycle and are structurally smaller. They produce thinner and shorter hair, which results in less scalp coverage. Eventually these follicles can regress to a state where they produce no hair at all.

#### Treatment

The Company believes its dermal sheath cup (DSC) cell therapy offers several advantages over current hair loss solutions. The current gold standard in hair loss treatment is hair transplant surgery which requires the surgical removal of a prominent band of hair-bearing scalp or multiple micro-biopsies from the back of the head. This band of resected tissue or biopsies are then dissected into hair follicles consisting of one to three hairs which are then implanted into balding areas on the scalp. Often a number of similar procedures are required to achieve the desired result and the patient is limited by the number of hairs that can be redistributed. In contrast, RCH-01 involves the extraction of as few as 20 hair follicles from the back of the patient's scalp where healthy cycling hair follicles reside. The Company believes these cells are responsible for the continued health of the hair follicle and the normal cycling of the hair fiber. DSC cells are isolated from the hair follicles and are then replicated in culture at a cGMP compliant facility utilizing the Company's proprietary cellular replication process, and are then reintroduced back into balding areas on a patient's scalp. The implanted cells are expected to rejuvenate damaged quiescent hair follicles leading to the growth of new healthy hair fibers. The anticipated long-term result of RCH-01 injections is the restoration and maintenance of a patient's hair.

# Phase I Clinical Trial (Europe)

The primary protocol objective of the study was to assess the local (at treatment sites) safety profile of injections of autologous DSC cells at nine-months post-injection compared to placebo. Secondary protocol objectives were to assess systemic (overall) safety and efficacy (hair growth at treatment sites) at nine-month post-injection and local safety at 24-months post-injection. The nine-month interim analysis was designed to provide us with safety information to support the regulatory filing for a phase II clinical trial. The nine-month interim analysis results support the continued development of DSC cells for the treatment of androgenetic alopecia. Participants of the phase I clinical trial were followed for five years. The primary objective of the study was to provide long-term safety profile of injections of cultured DSC cells five years after injection compared to control. This objective was met with an announcement of the final data from this trial in Q1 2017. In addition to establishing safety of the product through five years of follow-up, the data announcement also included several successful data measurements related to increased hair density and stabilization of hair loss through the initial 24 months in which these measurements were taken.

# Dose-Finding Clinical Study (Japan)

In 2016, a clinical study was launched in Japan as two clinical sites with funding and product manufacturing provided by Shiseido. The study investigated three different one-time injections. This study was completed in 2019 and data from the randomized, double-blinded, placebo-controlled dose-finding clinical study involving 65 patients as published in the Journal for the American Academy of Dermatology (July 2020). The study was successful in meeting its endpoints and establishing important data regarding which dose was optimal in achieving desired clinical outcomes.

# Pivotal Clinical Study (Japan) Testing Repeated Injections

In early 2020, Shiseido publicly communicated its intention to fund a next-phase trial of RCH-01 in Japan investigating a series of injections. In October 2020, Shiseido announced that it had launched such a trial to test the efficacy of 'repeated' injections of RCH-01 in 36 male and female patients with hair loss due to androgenic alopecia. The primary clinical endpoint of the study is to measure changes in hair density twelve months after treatment. In addition to testing the impact of repeated injection (which has not yet been tested), the study protocol also involves the treatment of the entire area of the patient's hair loss (which has also not yet been tested).

The Company has designed a phase 2 clinical trial intended to measure efficacy of RCH-01 in a larger population of patients with mild to moderate androgenetic alopecia and answer critical questions related to dosing and treatment

frequency. The Company is currently engaged in molecular marker research which is expected to lead to improvements in the product identification, manufacturing, and its clinical effectiveness. The Company will await data from this research and until clinical-grade prototypes of the RCI-02 dermal injector are available for use in clinical studies prior to submitting the clinical trial application for a phase 2 study of RCH-01 for regulatory approval.

#### Collaboration Agreement

The Company has a Collaboration and Technology Transfer Agreement with Shiseido Company, Limited ("Shiseido"), one of the world's largest cosmetic companies. Both companies have agreed to work towards establishing a clinical research program in Asia, with the goal of increasing the available human clinical data on RCH-01. The Company anticipates that collaborative technology transfer will continue between the companies as any new improvements to the RCH-01 technology are developed by either party. This agreement gives Shiseido an exclusive geographic license to use the Company's RCH-01 hair regeneration technology in Japan, China, South Korea, Taiwan and the ASEAN countries representing a population of approximately 2.1 billion people. In mid-2016, Shiseido alleged RepliCel had breached its obligations in the agreement which Shiseido alleged were potentially terminal to future obligations pursuant to the agreement. RepliCel has vigorously denied the existence of such breach and insists on the ongoing validity of the respective obligations on both parties pursuant to the agreement. No litigation or the triggering of other dispute mechanisms has been entered into by either party and RepliCel management is actively seeking to continue discussions and/or negotiations with Shiseido to resolve the matter. Shiseido funded a hospitalsponsored clinical study of RCH-01 in Japan which is now complete. The clinical data produced in such a study is, by agreement, to be made available to the Company. The Company expects Shiseido to share the data from this study with the Company in compliance with the Agreement. The Company has delivered several demands for the delivery of the data which Shisedo have failed to satisfy to-date. Nonetheless Shiseido continues to fund clinical testing and development of RCH-01 in Japan such as the clinical study described above. The Company is now actively exploring its legal alternatives in the pursuit of a resolution to this disagreement.

# Intellectual Property

The Company has filed patent applications on the use of hair follicle derived stem cells. This family of patents describes methods for isolating stem cells from hair follicles, and the growth and use of these stem cells for the treatment of a variety of medical conditions (including hair loss). Within this portfolio, there are granted patents in Australia (AU 2003246521), Europe (EP 1509597), the United States (8431400) and Canada (2488057). An additional related patent application is also pending in the United States (USSN 16/032728).

RCI-02: Dermal Injector Device

#### Background

To support the Company's RCH-01 and RCS-01 products, the Company is developing a second generation dermal injector device. The RCI-02 Injector, the production design of which is now complete, will be able to deliver programmable volumes of substances into programmed depths to specific layers of the skin in a constant form with minimal pressure or shear stress, ensuring the injected substance is viable and healthy after application. By improving the conditions of substance delivery, the Company improves the chances of success in the treatment of the patient. A significant feature of the new device is the incorporation of a cooling element at the injection site, thus removing the need for an anesthetic. This is a significant improvement over current syringe-type devices where an anesthetic is required prior to injection.

The Company believes that this device will have applications in certain other dermatological procedures requiring injections of specific volumes of material at specific depths and as such, is actively exploring licensing opportunities in these areas. In addition to the programmable variables of volume and depth, the device will also have interchangeable heads for different injection procedures (single and multi-needle). The Company received its first functioning prototypes for testing in Q3 2017 and, as a result of extensive testing, made several improvements to the components and design to optimize desired functionality through the following 18 months. Final prototypes were signed off on in late 2019 and first run of commercial-grade units were ordered into production in early 2020. This production run has been delayed due to COVID-19-related shutdowns across the supply chain. The Company now expects to have its first samples of the commercial-grade units from this production run in Q2 2021. These units will

then be tested over the coming months and an application submitted to regulators for marketing approval. A CE mark will allow the Company to commercially launch RCI-02 in Europe. An FDA approval (such as a 501(k)) will allow the Company to commercially launch RCI-01 in the United States. Either one will allow the Company to launch sale of the device and consumables in countries which accept those approvals such as Hong Kong where YOFOTO is already licensed to distribute. The registration of European or US marketing approval in Hong Kong is expected to trigger a \$500,000 milestone payment from YOFOTO.

A proprietary needle head has also been developed and will have its own regulatory approval where needed. Only this needle-head will work with the device and will be sold/distributed exclusively by RepliCel and its agents. A novel splash guard has also been developed to work with the device and will have its own regulatory approval where needed. This guard will be sold/distributed exclusively by RepliCel and its agents.

Regulatory approval will also be obtained by RepliCel on the assembled syringe cartridge where needed. This is the only cartridge which will work with the device and will be sold/distributed exclusively by RepliCel and its agents.

# Collaboration Agreement

The Company has a Collaboration and Technology Transfer Agreement with YOFOTO (China) Health Industry Co. Ltd. ("YOFOTO"). YOFOTO has agreed to work towards commercializing the RCI-02 device in China. This agreement gives YOFOTO an exclusive 15-year geographic license to commercialize the Company's RCI-02 dermal injector in technology in Greater China (China, Hong Kong, Macau, and Taiwan).

## **Intellectual Property**

The Company has also filed numbers patents and patent applications on its dermal injection devices for the delivery of therapeutically useful cells, as well the delivery of various other injectables. Representative granted patents include in Europe (EP 2623146 and EP 2809381), and the United States (US 9616182). Additional related patent applications are also pending in a variety of other jurisdictions such as Australia, Canada, China, Europe, Hong Kong, Israel, Japan, South Korea, New Zealand, Singapore, Taiwan, and the United States (US Pub No. 20180021523).

Investment and U.S. Partnership - Mainpointe Pharmaceuticals, LLC

On January 22, 2021, RepliCel signed three strategic agreements with MainPointe consisting of a Share Purchase Agreement, a Distribution Agreement, and a Royalty Agreement. The strategic investment of \$2,700,000 under the Share Purchase Agreement from MainPointe will be spread over an 8-month period. Under the limited term distribution partnership for RepliCel's dermal injector and consumables (the "RepliCel Injector Product Line") in the United States, MainPointe has agreed to pay all costs related to securing FDA approvals to launch the RepliCel Injector Product Line in the U.S. market. The Royalty Participation Agreement provides MainPointe the right to be paid a portion of RepliCel's future royalty revenue stream earned from the sale of RCS-01, RCT-01, and RCH-01 products and any derivatives. A shareholder director of RepliCel is the Chief Technology Officer of MainPointe.

# Primary Deal Terms

In consideration for an investment of \$2,700,000 and the payment of all costs related to obtaining FDA approval for the Company's dermal injector and consumables, RepliCel has agreed to issue MainPointe up to an aggregate of four (4) million common shares, a right to participate in RepliCel's royalty revenue stream up to a of a maximum payout of 16 million US dollars, and certain distribution rights of RepliCel Injector Product Line in the United States. The investment will be made as to:

- \$500,000 within five (5) days of receipt of conditional approval from the TSX Venture Exchange (received in the three months ended March 31, 2021),
- \$1,200,000 by February 15, 2021 (received \$482,127 in the three months ended March 31, 2021 and \$717,873 on April 23, 2021),
- \$700,000 by April 21, 2021 (not yet received), and
- \$300,000 by August 21, 2021.

The common shares will be priced at the greater of \$0.675 or the Discounted Market Price as such term is defined in the Policies of the TSX Venture Exchange.

During the three-month period ended March 31, 2021, the Company received \$982,127 and the Company received a further \$717,873 subsequent to March 31, 2021. As at March 31, 2021, the Company issued 729,024 common shares (at market value of \$0.50 per share for recorded proceeds of \$364,512) upon the receipt of \$492,092 towards the first \$500,000. The receipt of \$490,000 accounts for 725,925 common shares issuable as per terms of the Agreement and has therefore been recorded as share subscription valued at \$272,222 as at March 31, 2021. On April 23, 2021, the Company issued 1,777,778 common shares to Mainpointe Pharmaceutical LLP upon receipt of \$717,873 (see Note 18).

Mainpointe is entitled to a royalty under the agreement equal to:

- a) 5% of the amounts earned by and paid to the Company from the sale of any of its "NBDS Products" defined as its RCS-01 (NBDS Fibroblast Therapy Treatment for Aging Skin), RCT-01 (NBDS Fibroblast Therapy Treatment for Chronic Tendinosis) and any other product which is comprised of the non-bulbar dermal sheath cells patented by the Company, and
- b) 20% of the amounts earned by and paid to the Company from the sale of any of its "DSC Products" defined as its RCH-01 (DSC Therapy for Treatment Androgenic Alopecia) and any other product which is comprised of the dermal sheath cup cells patented by the Company.

In consideration for paying all expenses required to obtain regulatory approval for the RepliCel Injector Product Line, the exclusive distribution rights shall commence upon receipt of regulatory approval to launch the RepliCel Injector Product Line in the U.S. market for a period expiring on the earlier of:

- a) four (4) years, or
- b) when MainPointe has earned USD \$2,000,000 in gross income from the sale of the products in the RepliCel Injector Product Line.

The Company will have the right, in its discretion, to buy out this exclusivity right for an amount equal to the netpresent value of profit to be earned on USD \$2,000,000 in gross income, plus a further amount in gross income that is equal to the regulatory approval costs

The strategic agreements were accounted for as a compound financial instrument. The obligation to pay royalties of \$16 million USD is classified as a financial liability and measured at amortized cost. Management estimated the present value of future cash flows over the expected term using the effective interest rate. The timing and amount of future cash flows are significant judgments that influence measurement of a financial liability on initial recognition. The effective interest rate should be reassessed at each reporting period end date based on the changes to the future cash flows and their timing. Management believes that accretion expense in the three-month period ended March 31, 2021 is insignificant, thus no accretion expense was recorded. The Company incurred no transaction costs to enter into these agreements.

#### **DISCUSSION OF OPERATIONS**

#### Three months ended March 31, 2021 compared to three months ended March 31, 2020

	Three months ended March 31			Change from 2020 to 2021			
		2021		2020	Increase/ (Decrease)		Percentage Change
Revenue	\$	88,434	\$	88,434	\$	_	100%
Expenses							
Research and development	\$	288,629	\$	151,498	\$	137,131	91%
General and administrative	\$	280,883	\$	248,089	\$	32,794	13%
Other items	\$	874,267	\$	67,222	\$	807,045	1201%
Total loss	\$	1,355,345	\$	378,375	\$	976,970	258%

There was \$88,434 (2020 - \$88,434) in the License fees revenue from the YOFOTO Licensing and Collaboration Agreement recorded for the three months ended March 31, 2021 and 2020.

Research and Development expenses totaled \$288,629 for the three months ended March 31, 2021 compared to \$151,498 for the three months ended March 31, 2020 representing an increase of \$137,131 or 91%. Research and Development expenses were higher during the three months ended March 31, 2021 than 2020 due to fact that the Company has restarted the research and development program as a result of more funding from the Investment and U.S. Partnership – signed with Mainpointe Pharmaceuticals, LLC. During the three- months ended March 31, 2021, the Company received \$982,092 from Mainpointe pursuant to the three strategic agreements with MainPointe consisting of a Share Purchase Agreement, a Distribution Agreement, and a Royalty Agreement. The strategic investment of \$2,700,000 under the Share Purchase Agreement from MainPointe will be spread over an 8-month period. Under the limited term distribution partnership for RepliCel's dermal injector and consumables (the "RepliCel Injector Product Line") in the United States, MainPointe has agreed to pay all costs related to securing FDA approvals to launch the RepliCel Injector Product Line in the U.S. market. The Royalty Participation Agreement provides MainPointe the right to be paid a portion of RepliCel's future royalty revenue stream earned from the sale of RCS-01, RCT-01, and RCH-01 products and any derivatives. A shareholder director of RepliCel is the Chief Technology Officer of MainPointe.

General and administrative expenses for the three months ended March 31, 2021 totaled \$280,883 compared to \$248,089, an increase of \$32,794 or 13%. The Company, while it obtained financing from Mainpointe, focused its spending on research and development activities and made its best effort to maintain its general and administrative expenses to a minimum.

The loss from "Other items" for the three months ended March 31, 2021 of \$874,627 compared to \$67,222 was primarily due to the recording of a loss on re-measurement of a derivative liability assumed in the strategic agreements with Mainpointe in the amount of \$791,128. The fair value of the derivative liability is estimated as the difference between the market price of common share of RepliCel on measurement date and inception date [January 22, 2021] multiplied by the number of common shares issuable per the contractual terms. The derivative liability is re-measured until the settlement date, (when agreed proceeds for the Company's common shares have been received) with a gain or loss on re-measurement recognized on the Statement of profit or loss.

Total comprehensive loss for the three months ended March 31, 2021 was \$1,355,345 or \$0.04 per share on a basic and diluted basis compared to a net loss of \$378,375 or \$0.01 per share on a basic and diluted basis for the three months ended March 31, 2020.

#### SUMMARY OF QUARTERLY RESULTS

The following is a summary of the Company's financial results for the eight most recently completed quarters in accordance with IFRS.

	Mar 31, 2021 \$	Dec 31, 2020 \$	Sept 30, 2020 \$	June 30, 2020 \$	Mar 31, 2020 \$	Dec 31, 2019 \$	Sept 30, 2019 \$	June 30, 2019 \$
Revenues	88,434	88,434	88,434	88,434	88,433	88,434	88,434	88,434
Net loss	(1,355,345)	(254,437)	(597,994)	(349,478)	(378,376)	(1,093,452)	(589,550)	(950,748)
Basic and diluted loss per share	(0.04)	(0.02)	(0.02)	(0.01)	(0.01)	(0.02)	(0.02)	(0.04)

## LIQUIDITY AND CAPITAL RESOURCES

The Company's condensed consolidated interim financial statements have been prepared on a going concern basis which assumes that the Company will continue to realize its assets and discharge its obligations and commitments in the normal course of operations. Since its inception, the Company had accumulated \$5,083,967 in revenue from its business, had accumulated deficit of \$39,513,672 since incorporation and expected to incur further losses in the development of its business, which casts substantial doubt about the Company's ability to continue as a going concern. At March 31, 2021, the Company had current liabilities in excess of current assets of \$2,107,856. Additional working capital will be required for research and development along with general and administrative expenses and to further its business plans. The Company is currently pursuing both dilutive and non-dilutive financing it expects will satisfy its working capital requirements going forward. Non-dilutive funding includes grant funding and strategic partnerships involving product licenses to defined geographic markets and for specified applications. The Company's financial statements do not include any adjustments relating to the recoverability and classification of recorded assets, or the amounts of and classification of liabilities that might be necessary in the event that the Company cannot continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to generate future profitable operations and/or to obtain the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they come due. The Company has financed its operations to date through the issuance of equity. The continued volatility in the financial equity markets may make it difficult to raise funds by private placements of shares. There is no assurance that the Company will be successful with its financing ventures.

#### Operating Activities

During the three-months period ended March 31, 2021, \$536,341 was used in net cash from operating activities compared to \$38,372 of cash used in operating activities for the three-months period ended March 31, 2020. The increase in cash used for operating activities was a result of primarily increases in both research and development as well as general and administration activities due to increase in financial resources and a renewed focus on it research and development programs.

Additional working capital will be required for research and development and general administration expenses and to further our business plans.

#### Financing Activities

During the three-months ended March 31, 2021, \$983,891 was provided by financing activities compared to \$Nil for the same period in the prior year. The increase in financing activities resulting from the signing of the three strategic agreements signed with Mainpointe Pharmaceuticals, LLC. (see above section "Overall Performance").

#### **Going Concern**

The condensed interim consolidated financial statements prepared as at March 31, 2021 have been prepared on a going concern basis, which assumes that the Company will continue to realize its assets and discharge its obligations and commitments in the normal course of operations. At March 31, 2021, the Company is in the research stage, has accumulated losses of \$39,513,672 since its inception and expects to incur further losses in the development of its business. The Company incurred a consolidated net loss of \$1,355,345 during the three-month period ended March 31, 2021. As at date of this report, the Company will require additional funding to continue its research and development activities which may not be available, or available on acceptable terms. This will result in material uncertainties which casts substantial doubt about the Company's ability to continue as a going concern.

The Company's ability to continue as a going concern is dependent upon its ability to generate future profitable operations and/or to obtain the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they come due. Management has a plan in place to address this concern and intends to obtain additional funds by equity financing to the extent there is a shortfall from operations. While the Company is continuing its best efforts to achieve the above plans, there is no assurance that any such activity will generate funds for operations.

If the going concern assumptions were not appropriate for these condensed consolidated financial statements, then adjustments would be necessary to the carrying value of assets and liabilities, the reported net loss and the financial position classifications used.

We anticipate that we will require a maximum of approximately \$1,020,000, in addition to the investment committed by MainPointe, to proceed with our full current plan of operations for the twelve-month period ended December 31, 2021 focused on (1) progressing the RCI-02 device and consumables toward market launch in Europe and Hong Kong, (2) progressing toward the launch of clinical studies in Japan for RCS-01 and RCT-01, and (3) providing technology transfer, training and other support to be ready for clinical trial launch of RCS-01 and RCT-01 in China with our partner, YOFOTO.

The Company does not currently have sufficient capital resources to fund its full plan or operations for the next twelve months. Accordingly, the Company plans to raise additional capital through the sale of debt or equity securities or through other forms of financing in order to raise the funds necessary to pursue the Company's plan of operations. The Company currently does not have any arrangements in place for the completion of any financings and there is no assurance that it will be successful in completing any financings. The Company is currently pursuing both dilutive and non-dilutive financing it expects will satisfy its working capital requirements going forward. Non-dilutive funding includes grant funding and strategic partnerships involving product licenses to defined geographic markets and for specified applications. There can be no assurance that additional financing will be available when needed or, if available, on commercially reasonable terms. If the Company is not able to obtain additional financing on a timely basis, it may not be able to pursue its plan of operations or meet its obligations as they come due, and may be forced to scale down, or perhaps even cease, business operations. The Company is currently actively engaged in several due diligence reviews and partnership discussions. All such discussions involve the injection of new capital into the Company.

Cash on hand and cash equivalents are currently the Company's only source of liquidity. The Company does not have any lending arrangements in place with banking or financial institutions and the Company does not know whether it will be able to secure such funding arrangements in the near future.

#### **OUTSTANDING SHARE DATA**

Common Shares Outstanding

As of May 31, 2021, there were 36,161,601 common shares issued and outstanding.

As of May 31, 2021, there were stock options entitling the holders to acquire an aggregate of 1,725,000 common shares.

As of May 31, 2021, there were share purchase warrants outstanding entitling the holders to acquire an aggregate of 1,819,555 common shares.

As of May 31, 2021, there were no agent's options outstanding.

As at May 31, 2021, there were 1,089,125 preferred shares issued and outstanding.

#### RELATED PARTY TRANSACTIONS

# Related party balances

The following amounts due to related parties are included in accounts payable and accrued liabilities:

	31-March-2021	31-March-2020
Companies controlled by directors of the Company (a)	\$ 79,567	\$ 55,200
Directors or officers of the Company	147,285	73,427
	\$ 226,852	\$ 128,627

(a) These amounts are unsecured, non-interest bearing and have no fixed terms of repayment.

The Company incurred the following transactions with companies that are controlled by directors and/or officers of the Company. The transactions were measured at the amount agreed to by the parties.

	Three months ended			
	31-March- 2021		31-March- 2020	
Research and development	\$ 17,314	\$	18,600	
	\$ 17,314	\$	18,600	

#### **Key management compensation**

Key management personnel are persons responsible for planning, directing and controlling the activities of an entity, and include executive directors, the Chief Executive Officer and the Chief Financial Officer.

	Three months ended			
	31-March- 2021		31-March- 2020	
General and administrative - salaries	\$ 84,000	\$	84,000	
Directors' fees	17,750		14,500	
Stock-based compensation	-		2,314	
	\$ 101,750	\$	100,814	

#### **Preference shares**

During the year-ended December 31, 2020, three directors of the Company purchased 325,000 preference shares for \$130,000 (Note 8) in total. Accrued dividends to these three directors was \$14,156 as at March 31, 2021 (\$nil – March 31, 2020).

#### OFF BALANCE SHEET ARRANGEMENTS

As at May 30, 2021, the Company did not have any off-balance sheet arrangements, as defined by applicable securities regulators in Canada and the United States that have, or are material effect on our results of operations or financial position.

# PROPOSED TRANSACTIONS

None.

# **EVENTS AFTER REPORTING DATE**

Dividends - Preferred Shares / Shares for Debt

On March 31, 2021, the Company has announced its intention to pay accrued dividends of \$47,437 outstanding on the Class A Preferred Shares (the "Dividend Payment") in common shares (each, a "Share") of the Company at a price of \$0.375 per Share.

On April 19, 2021, the TSX Venture Exchange approved the settlement of \$47,437 in accrued dividends via issuance of 126,492 common shares at the price of \$0.375. Of the \$47,437 accrued dividends, \$14,156 were owed to certain directors of the Company.

Shares issued – Mainpointe Pharmaceutical LLC.

On April 23, 2021, the Company issued 1,777,778 common shares to Mainpointe Pharmaceutical LLP upon receipt of \$717,872.

#### Share for debt settlement

On May 27, 2021, the TSX Venture Exchange has conditionally approved the settlement of \$342,500 in outstanding debt via issuance of 889,612 common shares at a deemed price of \$0.385. Of the \$342,500, \$133,702 were owed to certain directors of the Company.

#### CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

RepliCel Life Sciences Inc. makes estimates and assumptions about the future that affect the reported amounts of assets and liabilities. Estimates and judgements are continually evaluated based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. In the future, actual experience may differ from these estimates and assumptions.

The effect of a change in an accounting estimate is recognized prospectively by including it in comprehensive income in the period of the change, if the change affects that period only, or in the period of the change and future periods, if the change affects both.

Information about critical judgments in applying accounting policies that have the most significant risk of causing material adjustment to the amounts reported in these financial statements are discussed below:

#### Share Based Payments

The Company measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Estimating fair value for share-based payment transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires determining the most appropriate inputs to the valuation model including the expected life of the share option, volatility and dividend yield and making assumptions about them. The assumptions and models used for estimating the fair value for share-based payment transactions are disclosed in Note 12(e) to the consolidated financial statements.

#### **Revenue Recognition**

The Company applies the five-step model to contracts when it is probable that the Company will collect the consideration that it is entitled to in exchange for the goods and services transferred to the customer. For collaborative arrangements that fall within the scope of IFRS 15, the Company applies the revenue recognition model to part or all of the arrangement, when deemed appropriate. At contract inception, the Company assesses the goods or services promised within each contract that falls under the scope of IFRS 15, to identify distinct performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied. Significant judgement is involved in determining whether the transaction price allocated to the license fee should be recognized over the collaboration period or at the inception of the contract and the time period over which revenue is to be recognized.

In the Share Purchase Agreement with YOFOTO, the Company issued shares to YOFOTO which had an identifiable market value at the time the agreement was signed. The price YOFOTO paid for these shares, plus associated share-purchase warrants (which have now expired), was over the then-market price for these shares. In addition to the Share Purchase Agreement, the Company also entered into a Licensing and Collaboration Agreement (See Note 8 – December 31, 2020 year-end Audited Financial Statements - Licensing and Collaboration Agreement – YOFOTO (China) Health Industry Co. Ltd.) with YOFOTO in which the Company granted to YOFOTO product licenses and a put option. The Company's methodology used in assessing the value assigned to the put options, licenses, and purchase warrants granted in these agreements is outlined in Note 8 and 12 (b) v).

#### **Preference Shares**

RepliCel has issued preference shares which remain outstanding. These shares represent both equity in and a liability to the Company. Management is required to assess the fair value of the equity and liability components of the preference shares at the date they were issued. The Company is also required to assess the effective interest on the preference shares which indicate the amounts payable on redemption inclusive of dividends.

# **Put Liability**

As outlined above, RepliCel has assessed the fair value of the potential liability represented by the put option issued to YOFOTO which assessment is further disclosed in Note 8. The put liability is a financial liability recorded initially at the present value of the potential exercise price of the put. Management is required to assign a fair effective interest rate to use in appropriately discounting the potential exercise price over the term of the put liability to its fair value at issuance.

# Investment and U.S. Partnership – Mainpointe Pharmaceuticals, LLC

The strategic agreements were accounted for as a compound financial instrument. The obligation to pay royalties of \$16 million USD is classified as a financial liability and measured initially at fair value and subsequently at amortized cost. Management estimated the present value of future cash flows over the expected term using the effective interest rate. The timing and size of future cash flows are significant judgments that influence measurement of this financial liability subsequent to its initial recognition. The effective interest rate is reassessed at each reporting period end date based on the changes to the future estimated cash flows and their timing. Management believes that accretion expense in the three-month period ended March 31, 2021 is insignificant, thus no accretion expense was recorded. The Company incurred no transaction costs to enter into these agreements.

The arrangement with MainPointe was accounted for as a hybrid instrument with two components: royalty payable, which is a financial liability accounted for initially at fair value and subsequently at amortized cost, and an obligation to issue common shares to MainPointe at an agreed price at a future date, which is a derivative liability accounted for FVTPL.

The fair value of the derivative liability related to the Company's obligation to issues its common shares at a future date at an agreed price is estimated as the difference between the market price of the Company's common shares on the measurement date and their market price on the inception date of the Mainpointe agreement (January 22, 2021) multiplied by the number of common shares issuable per the contractual terms. The derivative liability is remeasured until the settlement date, (when agreed proceeds for the Company's common shares have been received) with a gain or loss on remeasurement recognized on the Statement of profit or loss.

The royalty payable is recognized upon receipt of the proceeds from the issuance of commons shares and is measured as proceeds received less any derivative liability recorded based on the difference between the Company's common shares on the measurement date and the Mainpointe agreement inception date as outlined above. The royalty payable is then accreted using the effective interest rate over future reporting periods. The effective interest rate is reassessed at each reporting period end date based on changes to future cash flows and their timing.

MainPointe paid \$982,092 out of the \$2,700,000 contractually obligated as at March 31, 2021 and a further \$717,908 after March 31, 2021. See Note 7 to the condensed consolidated interim financial statements for a description of the Mainpointe agreement.

#### **Income Taxes**

Significant judgment is required in determining the provision for income taxes. There are many transactions and calculations undertaken during the ordinary course of business for which the ultimate tax determination is uncertain. The Company recognizes liabilities and contingencies for anticipated tax audit issues based on the Company's current understanding of the tax law. For matters where it is probable that an adjustment will be made, the Company records its best estimate of the tax liability including the related interest and penalties in the current tax provision. Management

believes they have adequately provided for the probable outcome of these matters; however, the final outcome may result in a materially different outcome than the amount included in the tax liabilities.

In addition, the Company will recognize deferred tax assets relating to tax losses carried forward to the extent there are sufficient taxable temporary differences relating to the same taxation authority and the same taxable entity against which the unused tax losses can be utilized. However, utilization of the tax losses also depends on the ability of the taxable entity to satisfy certain tests at the time the losses are recouped.

#### FINANCIAL INSTRUMENTS AND OTHER INSTRUMENTS

As at March 31, 2021, the Company's financial instruments are comprised of cash and cash equivalents, accounts payable and accrued liabilities, CEBA loan payable, preference shares, promissory note, put liability, derivative liability and royalty payable. The fair values of cash and cash equivalents, accounts payable and accrued liabilities, CEBA loan and promissory note approximate their carrying value due to their short-term maturity. The Company is exposed through its operations to currency, credit, liquidity and interest rate risk.

The fair value of the derivative liability at each reporting period is estimated using Level 2 inputs of the fair value hierarchy. Fair value of derivative liability was determined by multiplication of the following:

A - a number of common shares issuable to MainPointe in accordance with contractual terms using the expected issue price of \$0.675 for the Company's common share, and

B – a difference in market price of common share of the Company between the inception date of strategic agreements with MainPointe and the reporting date.

The expected issue price of the Company's common share is a significant estimate. The Company estimates that a 5% change in the issue price of the Company common share, holding other assumptions constant, would have changed the fair value of derivative liability by approximately \$21,000 as at March 31, 2021.

In common with all other businesses, the Company is exposed to risks that arise from its use of financial instruments. For more information, see the Company's annual audited consolidated financial statements.

# RISKS AND UNCERTAINTIES

#### Risks Relating to the Company's Business

In addition to the other risks and uncertainties set out earlier in this MD&A, the Company is also exposed to the following risks and uncertainties:

The Company currently does not generate recurring revenue from its operations, and as a result, it faces a high risk of business failure.

The Company has generated \$5,083,967 in licensing revenues from its operations to date. This revenue was the payment of an upfront fee of \$4,120,400 pursuant to a Collaboration and Technology Transfer Agreement with Shiseido and the License and Collaboration Agreement with YOFOTO. This revenue was not recurring revenue from its operations and the Company may not obtain similar revenue in the future.

MainPointe Pharmaceuticals LLC - Royalty Participation, Share Purchase, and Distribution Agreements

RepliCel is at risk of a possibility of MainPointe not discharging its obligations in the Agreements such as not funding or adequately or fully funding all regulatory submission costs as defined in the Agreements. Additional risk to the Company exists in MainPointe not fully allocating sufficient 'internal' resources to support the regulatory submission defined in the Agreements. The Company is also at risk that MainPointe does not distributing or adequately distributing the products which are the subject of the Agreements. RepliCel is also at risk of MainPointe refusing to purchase the shares of the Company as agreed to in the Share Purchase Agreement.

#### YOFOTO - License and Collaboration Agreement

The Company is exposed to certain risks related to YOFOTO's inability to obtain local and/or national regulatory approvals required to commercialize its licensed products because of factors outside of their control or ability to impact. Under such conditions, the License and Collaboration Agreement contains a provision permitting YOFOTO to put up to 2/3 of the shares issued in YOFOTO's initial investment back to the Company, if all conditions are met, for a period of 8.5 years from July 10, 2018.

The deal structure also includes milestone payments (of up to CDN \$4,750,000), sales royalties, and a commitment by YOFOTO to spend a minimum of CDN \$7,000,000 on the RepliCel programs and associated cell processing manufacturing facility over the next five years in Greater China pursuant to a License and Collaboration Agreement. The License and Collaboration Agreement contains a provision permitting YOFOTO to put up to 1/3 of the shares issued in YOFOTO's initial investment back to the Company under certain conditions for a period of 8.5 years from July 10, 2018.

RepliCel is at risk of a possibility of YOFOTO not being able to discharge its obligations in the Agreement and thereby causing RepliCel not to receive its scheduled milestone payments. Should it be deemed not to be YOFOTO's fault in not meeting its milestone targets, the Company may have the risk of having YOFOTO exercising its put options and have RepliCel buy back 2/3 of the shares.

There is a potential risk of YOFOTO not protecting RepliCel's intellectual property in the Licensed Territory in the event an actual or alleged infringement, by a third party, of the Licensed Technology or the Issued Patents or any right with respect to the Licensed Technology or the Issued Patents in the License Territory.

As of March 31, 2021, the Company had an accumulated deficit of \$39,513,672 since inception. The Company's business is focused on developing autologous cell therapies that treat functional cellular deficits including chronic tendon injuries, androgenetic alopecia and skin aging. In order to generate revenues, the Company will incur substantial expenses in the development of its business. The Company therefore expect to incur significant losses in the foreseeable future. The Company recognizes that if it is unable to generate significant revenues from its activities, the Company's entire business may fail. There is no history upon which to base any assumption as to the likelihood that the Company will be successful in its plan of operation, and the Company can provide no assurance to investors that it will generate operating revenues or achieve profitable operations in the future.

The Company had cash and cash equivalents in the amount of \$481,913 and current liabilities in excess of current assets of \$2,107,856 as of March 31, 2021 and the Company anticipates that it will require approximately \$1,020,000 in addition to the committed \$2,700,000 investment by MainPointe in 2021, to proceed with its current plan of operations focused on completing the RCI-02 device and preparing the regulatory application for marketing approval, meeting its obligations to support YOFOTO's activities in Greater China, and preparing for next-phase clinical development and commercialization in Japan over the twelve-month period ending March 31, 2022.

In order to fund its plan of operations for the next twelve months, the Company may seek to sell additional equity or debt securities or obtain a credit facility. The sale of convertible debt securities or additional equity securities could result in additional dilution to its shareholders. The incurrence of indebtedness would result in increased debt service obligations and could result in operating and financing covenants that would restrict its operations and liquidity.

Management has concluded that substantial doubt exists about the Company's ability to continue as a going concern.

The Company has incurred a deficit of \$39,513,672 for the cumulative period from September 7, 2006 (inception) to March 31, 2021. The Company anticipates generating losses for at least the next 12 months. Therefore, there is substantial doubt about its ability to continue operations in the future as a going concern, as described in Note 2a) of the Company's audited consolidated interim financial statements. The Company's financial statements do not include any adjustments relating to the recoverability and classification of recorded assets, or the amounts of and classification of liabilities that might be necessary in the event that the Company cannot continue in existence. The Company's business operations may fail if its actual cash requirements exceed its estimates and the Company is not able to obtain further financing. If the Company cannot continue as a viable entity, its shareholders may lose some or all of their investment in the Company.

The Company's business is at an early stage of development and difficulties obtaining regulatory approval, technical deficiencies and other challenges may hinder the development and marketing of its autologous cell therapies.

The Company's autologous cell therapy technology is at an early stage of development and the Company may not develop a cell replication technology that can be commercialized. The Company is still in the early stages of identifying and conducting research on its technology. The Company's technology will require significant research and development and preclinical and clinical testing prior to regulatory approval, if required, being obtained in the United States or other countries. The Company may not be able to obtain regulatory approvals, if required, to complete necessary clinical trials for its cell replication technology, or to commercialize it. The Company's technology may prove to have undesirable and unintended side effects, or other characteristics adversely affecting its safety, efficacy or cost-effectiveness could prevent or limit its use. The Company's technology may fail to provide its intended benefit, or achieve benefits equal to or better than its competitor's products at the time of testing or production and, if so, its business may fail.

The Company's clinical trials may fail to produce successful results or could be suspended due to unacceptable safety risks, which could cause its business to fail.

Clinical trials are subject to extensive regulatory requirements, and are very expensive, time-consuming and difficult to design and implement, in part because they may be subject to rigorous regulatory requirements. The Company's products may fail to achieve necessary safety and efficacy endpoints during clinical trials. The Company believes that its clinical trials will take a substantial period of time to complete. Furthermore, failure can occur at any stage of the trials, and the Company could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including: unforeseen safety issues; lack of effectiveness during clinical trials; slower than expected rates of patient recruitment; and inability to monitor patients adequately during or after treatment. In addition, the Company or regulatory officials may suspend the Company's clinical trials at any time if it appears that the Company is exposing participants to unacceptable health risks. If the Company's clinical trials fail to produce successful results, or are suspended due to unacceptable safety risks, the Company's business may fail.

The Company's success depends on the acceptance of its cell replication technology by the medical community and consumers as a safe and effective solution.

The success of its cell replication technology will depend on its acceptance by potential consumers and the medical community. Because its technology is new in the treatment of functional cellular deficits including chronic tendon injuries, androgenetic alopecia and skin aging, the long term effects of using its new cell replication technology are unknown. The results of short-term clinical trials do not necessarily predict long-term clinical benefit or reveal adverse effects. If results obtained from future commercial experience indicate that its cell replication technology is not as safe or effective as other treatments, adoption of this technology by consumers and the medical community may suffer and its business will be harmed.

The Company faces significant competition and if it is unable to successfully compete, the Company's business may suffer a material negative impact.

The life sciences industry is highly competitive. The Company anticipates that it will continue to face increased competition as existing companies develop new or improved products and as new companies enter the market with new technologies. Many of its competitors are significantly larger than us and have greater financial, technical, research, marketing, sales, distribution and other resources than us. There can be no assurance that its competitors will not succeed in developing or marketing technologies and products that are more effective or commercially attractive than the products the Company is developing or that such competitors will not succeed in obtaining regulatory approval, or introducing or commercializing any such products, prior to us. Such developments could have a material adverse effect on its business, financial condition and results of operations. Also, even if the Company is able to compete successfully, there can be no assurance that it could do so in a profitable manner.

If the Company is not able to effectively protect its existing intellectual property, the Company's business may suffer a material negative impact and may fail.

The success of the Company will be dependent on its ability to protect and develop its technology. The Company currently has registered patents for its cell replication technology in Australia, the United States, Japan and the European Union. If the Company is unable to protect its intellectual property, its business may be materially adversely affected. Further, the Company cannot be sure that its activities do not and will not infringe on the intellectual property rights of others. If the Company is compelled to prosecute infringing parties, defend its intellectual property or defend itself from intellectual property claims made by others, it may face significant expense and liability, as well as the diversion of management's attention from the Company's business, any of which could negatively impact its business or financial condition.

The actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends on many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patents. The Company's ability to maintain and solidify its proprietary position for its products will depend on its success in obtaining effective claims and enforcing those claims once granted. The Company's registered patents and those that may be issued in the future, or those licensed to us, may be challenged, invalidated, unenforceable or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar products. The Company also relies on trade secrets to protect some of its technology, especially where it is believed that patent protection is not appropriate or obtainable. However, trade secrets are difficult to maintain. While the Company uses reasonable efforts to protect its trade secrets, its employees, consultants, contractors or scientific and other advisors may unintentionally or wilfully disclose the Company's proprietary information to competitors. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. In addition, non-U.S. courts are sometimes less willing than U.S. courts to protect trade secrets. If the Company's competitors independently develop equivalent knowledge, methods and know-how, the Company would not be able to assert its trade secrets against them and its business could be harmed.

The successful acquisition and maintenance of patent rights is critical to its business and any failure in this regard could hinder the development and marketing of its technology.

The Company currently has patent applications pending in several other countries around the world. The Company's pending patent applications may not result in the issuance of any patents. The applications may not be sufficient to meet the statutory requirements for patentability in all cases or may be the subject of interference proceedings by patent offices. These proceedings determine the priority of inventions and, thus, the right to a patent for technology. In the past, its patent applications have experienced delays and its patent applications may be delayed in the future. If others file patent applications or obtain patents similar to those the Company has licensed, such patents may restrict the use of its discoveries. The Company cannot predict the ultimate scope and validity of existing patents and patents that may be granted to third parties, nor can it predict the extent to which it may wish or be required to obtain licenses to use such patents, or the availability and cost of acquiring such licenses. To the extent that licenses are required, the owners of the patents could bring legal actions against us to claim damages or to stop its manufacturing and marketing of the affected technology. If the Company becomes involved in patent litigation, it could consume a substantial portion of its resources.

The Company may be subject to changes and uncertainties in laws and government regulations.

The Company is subject to regulation by domestic and foreign governmental agencies with respect to many aspects of developing autologous cell replication technology. In addition, relevant new legislation or regulation could occur. Any such new legislation or regulation, the application of laws and regulations from jurisdictions whose laws do not currently apply to the Company's business, or the application of existing laws and regulations to cell replication technology, could have a material adverse effect on the Company's business, prospects, financial condition and results of operations.

# Risks Relating to the Company's Management

The Company is dependent on the services of certain key consultants and the loss of any of these key consultants may have a materially adverse effect on the Company.

While engaged in the business of developing a new cell replication technology, the Company's ability to continue to develop a competitive edge in the marketplace will depend, in large part, on its ability to attract and maintain qualified key management personnel. Competition for such personnel is intense, and it may not be able to attract and retain such personnel. The Company's growth has depended, and in the future will continue to depend, on the efforts of its key management consultants. Loss of any of these people would have a material adverse effect on the Company. Currently, the Company does not have key-man life insurance.

Conflicts of interest may arise as a result of the Company's directors and officers being directors or officers of other life sciences companies.

Certain of the Company's directors and officers are, or may become, directors or officers of other life sciences companies. While the Company is engaged in the business of developing a new autologous cell replication technology, such associations may give rise to conflicts of interest from time to time. The Company's directors are required by law to act honestly and in good faith with a view to the Company's best interests and to disclose any interest that they may have in any project or opportunity. If a conflict of interest arises at a meeting of the Company's board of directors, any director in a conflict must disclose his interest and abstain from voting on such matter. In determining whether or not the Company will participate in any project or opportunity, the Company's directors will primarily consider the degree of risk to which the Company may be exposed and its financial position at the time.

The Company's articles contain provisions indemnifying its officers and directors against all costs, charges and expenses incurred by them.

The Company's articles contain provisions limiting the liability of its officers and directors for all acts, receipts, neglects or defaults of themselves and all of its other officers or directors or for any loss, damage or expense incurred by the Company which may happen in the execution of the duties of such officers or directors. Such limitations on liability may reduce the likelihood of derivative litigation against the Company's officers and directors and may discourage or deter its shareholders from suing the Company's officers and directors based upon breaches of their duties to the Company, though such an action, if successful, might otherwise benefit the Company and its shareholders.

As a majority of the Company's directors and officers are residents of countries other than the United States, investors may find it difficult to enforce, within the United States, any judgments obtained against the Company, directors and officers.

A majority of the Company's directors and officers are nationals and/or residents of countries other than the United States, and all or a substantial portion of such persons' assets are located outside the United States. Consequently, it may be difficult for United States investors to effect service of process in the United States upon those directors or officers who are not residents of the United States, or to realize in the United States upon judgments of United States courts predicated upon civil liabilities under United States legislation. There is substantial doubt whether an original action based solely upon such civil liabilities could be brought successfully in Canada against any of such persons or the Company.

#### Risks Relating to the Company's Common Stock

If the Company's business is unsuccessful, its shareholders may lose their entire investment.

Although shareholders will not be bound by or be personally liable for its expenses, liabilities or obligations beyond their total original capital contributions, should it suffer a deficiency in funds with which to meet its obligations, the shareholders as a whole may lose their entire investment in the Company.

Trading of the Company's common shares on the OTCQB (operated by the OTC Markets Group) and the TSX Venture Exchange is limited and sporadic, making it difficult for the Company's shareholders to sell their shares or liquidate their investments.

The trading price of the Company's common shares has been and may continue to be subject to wide fluctuations. The stock market has generally experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies with little or no current business operations. There can be no assurance that trading prices and price earnings ratios previously experienced by the Company's common shares will be matched or maintained. These broad market and industry factors may adversely affect the market price of the common shares, regardless of the Company's operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted. Such litigation, if instituted, could result in substantial costs for the Company and a diversion of management's attention and resources.

Investors' interests in the Company will be diluted and investors may suffer dilution in their net book value per share if it issues additional options to any of its officers, directors, employees or consultants.

Because the Company's success is highly dependent upon its directors, officers and consultants, it has granted, and may again in the future grant, options to some or all of its key officers, directors, employees and consultants to purchase its common shares as non-cash incentives. Options may be granted at exercise prices below that of its common shares prevailing in the public trading market at the time or may be granted at exercise prices equal to market prices at times when the public market is depressed. To the extent that significant numbers of such options may be granted and exercised, the interests of the Company's other shareholders may be diluted.

Investors' interests in the Company will be diluted and investors may suffer dilution in their net book value per share if the Company issues additional shares or raises funds through the sale of equity securities.

In the event that the Company is required to issue additional shares in order to raise financing, investors' interests in the Company will be diluted and investors may suffer dilution in their net book value per share depending on the price at which such securities are sold. The dilution may result in a decline in the market price of the Company's shares.

Penny stock rules limit the ability of the Company's shareholders to sell their stock.

The Securities and Exchange Commission has adopted regulations which generally define "penny stock" to be any equity security that has a market price (as defined) less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exceptions. The Company's securities are covered by the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell to persons other than established customers and accredited investors. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the Securities and Exchange Commission, which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from these rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure

requirements may have the effect of reducing the level of trading activity in the secondary market for the stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade its securities.

The Financial Industry Regulatory Authority, or FINRA, has adopted sales practice requirements which may also limit a shareholder's ability to buy and sell the Company's stock.

In addition to the "penny stock" rules described above, FINRA has adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy its common stock, which may limit your ability to buy and sell its stock and have an adverse effect on the market for its shares.

The Company does not intend to pay dividends on any investment in the shares of stock of the Company.

The Company has never paid any cash dividends and currently do not intend to pay any dividends for the foreseeable future. To the extent that the Company requires additional funding currently not provided for in its financing plan, its funding sources may prohibit the payment of a dividend. Because the Company does not intend to declare dividends, any gain on an investment in the Company will need to come through an increase in the stock's price. This may never happen and investors may lose all of their investment in the Company.

#### OTHER INFORMATION

The Company's website address is www.replicel.com. Other information relating to the Company may be found on SEDAR at www.sedar.com

### **BOARD APPROVAL**

The board of directors of the Company have approved this MD&A.