

**REPLICEL LIFE SCIENCES INC.**  
**MANAGEMENT DISCUSSION AND ANALYSIS**  
**FORM 51-102F1**  
**For the period ended September 30, 2023**

**Dated as of November 28, 2023**

This Management's Discussion and Analysis ("MD&A") of RepliCel Life Sciences Inc (referred to as "RepliCel", the "Company", "us" or "our") provides analysis of the Company's financial results for the nine-month periods ended September 30, 2023. The following information should be read in conjunction with the accompanying annual financial statements for the year ended December 31, 2022, and the notes to those financial statements, prepared in accordance with IAS 34 under International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board. Financial information contained herein is expressed in Canadian dollars unless stated otherwise. Unless otherwise indicated, all information in this MD&A is current as of October 23, 2023. This MD&A is intended to supplement and complement RepliCel's financial statements for the period ended September 30, 2023, and the notes thereto. Readers are cautioned that this MD&A contains "forward-looking statements" and that actual events may vary from management's expectations. Readers are encouraged to read the cautionary note contained herein regarding such forward-looking statements. This MD&A was approved and authorized for issue by the Company's Audit Committee on behalf of our Board of Directors on November 28, 2023.

**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 regarding 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 and other countries 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;
- belief that regulatory agencies, including those in the United States, China, Europe, and Canada will approve applications to market the DermaPrecise product line without major objection or delay;
- research pertaining to and plans to continue to prepare for a phase 2 dose-finding trial for RCH-01 and details of such a trial;
- belief that the DermaPrecise trademark filings will be generally accepted in most jurisdictions where they are submitted;
- belief that the DermaPrecise 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 the regulatory agencies in China will approve applications to proceed with clinical studies of RCT-01 and RCS-01 in China without significant objection or delay;
- expectations that the Company will maintain patent protection over its technologies to maximize the financial value of its product prior to and through commercialization;

- belief as to the potential of the Company's products;
- expectations regarding the performance of its commercial partners, YOFOTO, and MainPointe;
- expectations regarding the payment of milestone payments by YOFOTO;
- 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;
- 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 associated with the loss or expiry of patent protections over the Company's technologies prior to the commercialization of the products related to those technologies and patents;
- risks and uncertainties associated with the Company's ability to raise additional capital;
- risks and uncertainties associated with supply chain issues caused by global and regional disruptions; 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.

## **DESCRIPTION OF BUSINESS**

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 OTC PK, 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 and 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.

## **HIGHLIGHTS OF BUSINESS**

### *The Potential of Autologous Cell Therapy*

The Company's treatments use autologous cell therapy ("ACT"), one of the most rapidly developing areas of regenerative medicine in developing 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, bio-incompatibility, 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 DermaPrecise (our dermal injection device and consumables). Our intellectual property portfolio includes patents and patent applications 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 general health. The Company believes that the current standard of care fails to provide a satisfactory solution to this chronic condition.

#### Treatment

The Company believes chronic tendon injuries resulting from sports-related or occupational overuse are 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. No adverse events were reported in these trials, where 90 patients were injected with cultured, autologous fibroblasts. 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. The trial design was randomized, double-blinded, and placebo-controlled with a treatment-to-placebo ratio 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. They are then reintroduced under ultrasound guidance directly into the area of the 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 in Q1 2017. The primary endpoint of safety was met, while secondary endpoints 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. The Company is preparing for a university-sponsored clinical research study of RCT-01 in patients with tendinopathy under that country's Act on the Safety of Regenerative Medicine (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 PMDA 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 about 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 treating and repairing 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. The 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, some studies report 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 the skin's mechanical tensile ability and structural integrity.

### 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 directly providing UV-naïve collagen-producing fibroblast cells 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 them 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 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 as 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.

All future clinical trials of RCS-01 will be intended to be conducted using prototypes of RepliCel's DermaPrecise 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 treating and repairing 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. Over \$3 billion is spent yearly on hair loss treatments that provide limited results. Androgenetic alopecia is largely an inherited disease. Males and females can inherit it 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.

### 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 the 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 months 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 treating androgenetic alopecia. Participants in the phase I clinical trial were followed for five years. The study's primary objective was to provide a 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 the product's safety 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 successfully met its endpoints and established 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 clinical study of RCH-01 in Japan investigating a series of injections. In October 2020, Shiseido announced that it had launched such a study 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). Shiseido has not reported any updates on the status of this study or any data from the study.

The Company has designed a phase 2 clinical trial intended to measure the 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 at the University of British Columbia, which is expected to lead to improvements in product identification, manufacturing, and clinical effectiveness. The Company will await data from this research and until clinical-grade prototypes of the DermaPrecise dermal injector are available for use in clinical studies before 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 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 Parties agreed to collaborate as any new improvements to the RCH-01 technology were developed by either party. This agreement gave 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 approximately 2.1 billion people. In mid-2016, Shiseido alleged RepliCel had breached its obligations in the agreement, which was potentially terminal to future obligations pursuant to the agreement. RepliCel has vigorously denied the existence of such a breach and insists on the ongoing validity of the respective obligations of both parties pursuant to the agreement. Despite the allegations of breach and termination, Shiseido funded a hospital-sponsored clinical study of RCH-01 in Japan, which is now complete. By agreement, the clinical data produced in the study is to be made available to the Company. The Company has delivered several demands for the delivery of the data, which Shiseido has refused. The company has made several other demands for compliance with different obligations in the Agreement. Shiseido has refused to comply with all demands. Nonetheless, Shiseido continues to fund clinical testing and development of RCH-01 in Japan, such as the Pivotal Clinical Study described above, which is still ongoing and incomplete. In 2021, the Company actively explored its legal alternatives in the pursuit of a resolution to this disagreement. In 2021 the Company attempted to engage Shiseido in settlement discussions by written letters, without success. The Company obtained a legal opinion from a lawyer about proceeding with arbitration. Based on that legal advice, the Company consulted with lawyers who specialize in international arbitration and retained a law firm based in Switzerland, Aceris Law, to represent the Company in the arbitration. The Company and Aceris Law filed a Notice of Arbitration with the International Center for Dispute Resolution (ICDR), the arbitral tribunal with jurisdiction over the Agreement between the Parties. The Company issued a Press Release advising shareholders of this milestone. Shiseido served the Company with its Response to the Notice of Arbitration, and the Company’s legal counsel reviewed Shiseido’s Response with the Company. Based on Shiseido’s Response to the Notice of Arbitration, the Company made a strategic and legally necessary step of terminating the Agreement with Shiseido.

In 2022, the Company’s legal counsel has continued to fulfil the procedural requirements of the ICDR arbitration process, which to date has included drafting and filing the Notice of Claim, vetting and agreeing to the arbitration panel, making procedural applications, drafting and filing the Statement of Claim and witness statements, corresponding with the panel and opposing counsel regarding the procedural calendar for the full arbitration process, etc. The Company has received the filed Statement of Defence by Shiseido’s counsel. An oral hearing was scheduled for May 29, 2023 to June 1, 2023 (completed). The Company expects to have a final, written decision by Q4 2023. In Q1 of 2023, preliminary discussions have been held between the Parties exploring potential settlement. The Company will continue to explore the opportunity to settle the dispute on terms favourable to shareholders, but there is no expectation that such a settlement will occur.



On October 16, 2023, the tribunal dismissed RepliCel's claims, finding that Shiseido validly terminated the collaboration and technology transfer agreement dated effective July 9, 2013. Management is currently considering the impact of the decision and assessing its options.

### Intellectual Property

The Company has filed patent applications for 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 treating various 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).

#### *DermaPrecise: 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 DermaPrecise 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 treating 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 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 prototypes was ordered into production in early 2020. This production run was delayed due to COVID-19-related shutdowns across the supply chain. The Company proceeded to produce its first samples of the commercial-grade prototypes in Q2 2021 and is in the early stages of functional and safety testing which is leading to minor design and production iterations based on results. The company has yet to sign off on a version of the device, which it believes is suitable for serial production. Once this stage of testing and component changes is complete, a full manufacturing run of units will be produced for testing over the following months and an application submitted to regulators for marketing approval. A CE mark will allow the Company to launch DermaPrecise in Europe commercially. An FDA approval (such as a 501(k)) will allow the Company to commercially launch the DermaPrecise Injector and single-use components 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.

RepliCel will also obtain regulatory approval on the assembled syringe cartridge where needed. This is the only cartridge that will work with the device and 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 DermaPrecise device in China. This agreement gives YOFOTO an exclusive 15-year geographic license to commercialize the Company’s DermaPrecise dermal injector in technology in Greater China (China, Hong Kong, Macau, and Taiwan).

### Intellectual Property

The Company has also filed a number of patents and patent applications on its dermal injection devices for the delivery of therapeutically useful cells, as well as 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: 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 and director of RepliCel is the Chief Technology Officer of MainPointe. The RepliCel and MainPointe teams actively collaborate on the US regulatory strategy and filing preparations.

### 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 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 (\$492,092 on February 8, 2021),
- \$1,200,000 by February 15, 2021 (received \$490,000 on March 23, 2021 and \$717,871 on April 23, 2021),
- \$700,000 by April 21, 2021 (received \$500,528 on August 30, 2021, \$199,472 received on November 29, 2021), and
- \$300,000 by August 21, 2021 (\$298,921 received on November 29, 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.

*Investment and U.S. Partnership – Mainpointe Pharmaceuticals, LLC – continued*

During the year ended December 31, 2021, the Company received the aggregate consideration of \$2,700,000 in five tranches which were accounted for and allocated as follows on initial recognition:

<b>Tranche receipt date</b>	<b>Tranche amount \$</b>	<b>Share capital or share subscription \$</b>	<b>Royalty payable \$</b>	<b>Loss on remeasurement of derivative liability \$</b>	<b>Derivative liability \$</b>
February 8, 2021	492,092	364,512	346,287	(218,707)	-
March 23, 2021	490,000	272,222	344,815	(127,037)	445,384
April 23, 2021	717,871	378,667	507,376	(168,172)	(163,892)
August 30, 2021	500,528	240,995	352,224	(92,691)	(225,991)
November 30, 2021	498,393	203,049	350,845	(55,501)	(55,501)
<b>Total*</b>	<b>2,698,884</b>	<b>1,459,445</b>	<b>1,901,547</b>	<b>(662,108)</b>	<b>-</b>

\* The difference of \$1,116 between the contractual gross proceeds and actual gross proceeds received is attributable to wire fees and foreign exchange translation differences.

The Company issued 3,986,684 common shares to fulfill its obligations pursuant to the Share Purchase Agreement:

<b>Issue Date</b>	<b>Number of common shares</b>
February 8, 2021	729,024
April 23, 2021	1,777,778
December 17, 2021	1,479,882
	<b>3,986,684</b>

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 selling 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 net present 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 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 at FVTPL.

*Investment and U.S. Partnership – Mainpointe Pharmaceuticals, LLC – continued*

The obligation to pay royalties of \$16 million USD is classified as a financial liability and measured initially at its fair value and subsequently at amortized cost. Management estimated the present value of future cash flows over the expected term using an estimated effective interest rate. The timing and amount of future cash flows are significant judgments that influence measurement of this financial liability over its term until settled. The effective interest rate will be reassessed at each reporting period end date based on management’s estimates of changes to the future cash flows and their timing. Management has recorded accretion expense of \$732,069 in the year ended December 31, 2021 based on an effective interest rate of 57%. The Company incurred no transaction costs to enter into these agreements.

Accretion expense recorded in the nine months ended September 30, 2023 of \$467,201 (2022: \$920,247) was based management’s estimate that they would pay USD \$16 million royalty obligation in 2.34 years (“the Payback Period”), commencing from January 1, 2024. On December 31, 2022, the Company changed the estimated commencement date from January 1, 2024, to January 1, 2026, based on new information. As a result of the change, the Company recognized a gain of \$3,310,875 in its statement of comprehensive loss. The change in commencement date did not impact the current estimated Payback Period, which remains at 2.34 years. Any changes in this estimated Payback Period would result in variability to the Company’s reported royalty obligation and annual accretion expense. Should the Payback Period extend beyond the current estimated 2.34 years, the royalty obligation at December 31, 2022, the accretion in the year ended December 31, 2022 and the effective interest rate estimate would change as presented below:

<b>Payback Period (years)</b>	<b>Royalty payable estimate at December 31, 2022 (\$)</b>	<b>Accretion expense for December 31, 2022 (\$)</b>	<b>Effective interest rate</b>
2.34 (current estimate)	1,623,088	2,031,758	57%
5.00	3,227,547	784,813	29%
7.50	2,969,087	606,255	24%
10.00	2,810,512	498,534	21%

**OTHER**

On November 28, 2022, the Company announced that Andrew Schutte has accepted the role of President and CEO. Mr. Schutte has served as a Director and has been a member of both the Science and Operations Committees since 2018. RepliCel's previous President and CEO, Mr. Lee Buckler, has resigned from these roles and will work with the Board on an ongoing basis. Mr. Buckler remains the Company's director.

In addition, Kevin McElwee, co-founder and Chief Science Officer, has agreed to oversee a robust and expanding set of research initiatives, Ben Austring has been appointed Corporate Secretary and Chief Operating Officer, and David Kwok has been appointed Chief Financial Officer after the sudden passing of Simon Ma in July 2023.

## DISCUSSION OF OPERATIONS

		<b>For the nine months ended September 30,</b>				
		<b>2023</b>		<b>2022</b>		<b>Variance</b>
<b>Revenue</b>	\$	265,302	\$	265,302	\$	-
<b>Expenses</b>						
Research and development		390,369		404,576		14,207
General and administrative		958,608		872,688		(85,920)
Other items		1,256,450		2,002,104		(745,654)
<b>Net loss</b>	\$	(2,340,125)	\$	(3,014,066)	\$	(817,367)

Research and Development expenses totalled \$390,369 for the nine months ended September 30, 2023, compared to \$404,576 for the same period ended in 2022. The variance is due to the re-execution of the planned projects.

General and administrative expenses totalled \$958,608 compared to \$872,688, a decrease of \$85,920 due to cost-saving initiatives by the Company. A significant portion of the G&A costs were due to legal fees in connection with the Company's arbitration hearings.

Loss from other items for the nine months ended September 30, 2023, was substantially less compared to the same period last year is primarily due to the revised estimate in accretion expense related to the royalty.

## SUMMARY OF QUARTERLY RESULTS

The following summarizes the Company's financial results for the eight most recently completed quarters.

	30-Sep-23	30-Jun-23	31-Mar-23	31-Dec-22	30-Sep-22	30-Jun-22	31-Mar-22	31-Dec-21
Revenues	\$ 88,434	\$ 88,434	\$ 88,434	\$ 88,434	\$ 88,434	\$ 88,434	\$ 88,434	\$ 88,434
Net loss	\$ (818,605)	\$ (558,151)	\$ (963,370)	\$ (496,876)	\$(1,115,698)	\$(1,111,037)	\$ (787,331)	\$ (832,991)
Basic and diluted loss per share	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.01)	\$ (0.03)	\$ (0.03)	\$ (0.02)	\$ (0.02)

## LIQUIDITY AND CAPITAL RESOURCES

The Company's condensed consolidated financial statements have been prepared on a going concern basis, assuming 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 \$5,968,304 in revenue from its business, had accumulated a deficit of \$45,314,995 since incorporation and is 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. On September 30, 2023, the Company had current liabilities in excess of current assets of \$1,318,864. Additional working capital will be required for research and development along with general and administrative expenses to further its business plans. The Company is pursuing both dilutive and non-dilutive financing, which it expects will satisfy its working capital requirements in the future. 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 if the Company cannot continue as a going concern.

The Company's ability to continue as a going concern depends on its ability to generate future profitable operations and/or 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 nine months ended September 30, 2023, \$1,751,575 was used in net cash from operating activities compared to \$1,168,813 of cash used in operating activities for the comparative period ended September 30, 2022. The increase in cash used for operating activities resulted primarily from increased resources due to the recent consecutive private placements. It is also due to a renewed focus on its research and development programs and arbitration costs with Shiseido.

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

### Financing Activities

During the nine month period ending September 30, 2023, the Company raised \$1,013,100 in private placement and settled \$383,171 in debt by issuing shares.

The Company's ability to continue as a going concern depends on its ability to generate future profitable operations and/or 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 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.

We anticipate requiring additional funds to proceed with our current plan of operations through December 31, 2023, focused on finalizing the DermaPrecise device and consumables for a marketing approval application to the US FDA and market launch in the United States and Hong Kong, progressing toward the launch of clinical studies in Japan for RCS-01 and RCT-01 should partners be secured to fund those studies, and providing technology transfer, training and other support to be ready for clinical trial launch of RCS-01 and RCT-01 in China.

In combination with potential revenue from milestone payments and/or upfront licensing fees received pursuant to potential new licensing deals, the Company anticipates that we will require a maximum of \$2,000,000 to proceed with our full current plan of operations through December 31, 2023. Accordingly, the Company plans to raise additional capital through the sale of debt or equity securities or other forms of financing in order to raise the funds necessary to pursue the Company's plan of operations.

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 cannot 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 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 at the date of this MD&A, there were 65,001,560 common shares issued and outstanding.

As at the date of this MD&A, there were stock options entitling the holders to acquire an aggregate of 4,075,000 common shares.

As at the date of this MD&A, share purchase warrants were outstanding entitling the holders to acquire an aggregate of 11,384,559 common shares.

As at the date of this MD&A, there were no agent's options outstanding.

As at the date of this MD&A, there were 1,089,125 preferred shares issued and outstanding.

## RELATED PARTY TRANSACTIONS

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

	<b>September 30, 2023</b>	September 30, 2022
Companies controlled by directors of the Company (a)	\$ -	\$ 47,250
Directors or officers of the Company	<b>99,195</b>	43,500
	<b>\$ 99,195</b>	\$ 90,750

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

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

	<b>Three months ended</b>	
	<b>September 30, 2023</b>	September 30, 2022
Research and development	\$ 15,000	\$ 15,000
	<b>\$ 15,000</b>	\$ 15,000

### Key management compensation

Key management personnel are people responsible for planning, directing and controlling the activities of an entity and include directors, the CEO, COO, and the CFO.

	<b>Nine months ended</b>	
	<b>September 30, 2023</b>	September 30, 2022
General and administrative - salaries	\$ 156,000	\$ 84,000
Directors' fees	<b>53,000</b>	<b>21,750</b>
Stock-based compensation	<b>264,554</b>	<b>104,995</b>
	<b>\$ 473,554</b>	\$ 210,745

## OFF BALANCE SHEET ARRANGEMENTS

As Date of this MD&A, 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.



## **EVENTS AFTER THE REPORTING DATE**

None that are not already disclosed.

## **CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS**

RepliCel 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 a 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.

### **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.

### **Preference Shares**

The Company made estimates on the issuance of preference shares, which are compound instruments that consist of both an equity and a liability component. Due to required redemption RepliCel preference shares were classified as liability. Management was required to make estimates to determine the fair value of the components of the preference share issuance on the date it is issued. The Company also needed to estimate the effective interest on preference shares to calculate the amounts payable on redemption and inclusive of dividends.

### **Put Liability**

The Company made estimates on the issuance of the put liability disclosed in the financial statements. 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 estimate to determine the effective interest rate to appropriately discount the potential exercise price over the term of the put liability to its fair value at issuance. Subsequent to its initial recording, the put liability is accreted up to the full face value at the end of the term of the agreement.

## **Derivative Liability**

Repliscel made estimates in determining the fair value of the derivative liability. The obligation to issue common shares to Mainpointe at an agreed price at a future date is a derivative liability accounted for at FVTPL. The fair value of this derivative liability has been estimated based on the difference between the market value of the Company's shares to be issued under this arrangement at the reporting date compared to the agreed price of such shares. The derivative liability is fair valued at each measurement date until its settlement.

## **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 September 30, 2023 and the date of this MD&A, 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.

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 \$6,056,738 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 \$1,582,601 pursuant to a License and Collaboration Agreement with YOFOTO for certain development and commercialization rights to certain products (the "Licensed Technology") for Greater China (Hong Kong, People's Republic of China, Macau, and Taiwan) (the "Licensed Territory"). 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.

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 anticipates that it will require approximately \$2,000,000 in the next twelve months to proceed with its current plan of operations focused on completing the DermaPrecise 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.

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 anticipates generating losses for at least the next twelve 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 or it expires prior to product commercialization, 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 and to do so prior to patent expiry. 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 Company lost its claims in the Arbitration and the Company's business has suffered a material negative impact and may fail.*

The tribunal dismissed RepliCel's claims finding that Shiseido validly terminated the collaboration and technology transfer agreement dated effective as of July 9, 2013. Management is currently considering the impact of the decision and assessing its options.

*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](http://www.replicel.com). Other information relating to the Company may be found on SEDAR at [www.sedar.com](http://www.sedar.com)

#### **BOARD APPROVAL**

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