



# **REVIVE THERAPEUTICS LTD.**

## **ANNUAL INFORMATION FORM**

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**For the Financial Year Ended June 30, 2020**

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**January 26, 2021**

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## GENERAL MATTERS

In this annual information form (“Annual Information Form” or “AIF”), references to the “Company”, “Corporation”, “Revive”, “we”, “us”, or “its” are references to Revive Therapeutics Ltd. References to “management” in this AIF mean the persons acting in the capacity of Revive’s Chief Executive Officer and Chief Financial Officer. Any statement in this AIF made by or on behalf of management are made in such person’s capacities as officers of Revive and not in their personal capacities. All references in this AIF to the Corporation also include references to all subsidiaries of the Corporation as applicable, unless the context requires otherwise.

Revive’s website is located at [www.revivetherapeutics.com](http://www.revivetherapeutics.com). The contents of Revive’s website are expressly not incorporated by reference into this AIF.

## MARKET AND INDUSTRY DATA

This AIF includes market and industry data that has been obtained from third party sources, including industry publications. The Corporation believes that its industry data is accurate and that its estimates and assumptions are reasonable, but there is no assurance as to the accuracy or completeness of this data. Third party sources generally state that the information contained therein has been obtained from sources believed to be reliable, but there is no assurance as to the accuracy or completeness of included information. Although the data is believed to be reliable, the Corporation has not independently verified any of the data from third party sources referred to in this AIF or ascertained the underlying economic assumptions relied upon by such sources.

## FORWARD-LOOKING STATEMENTS

This AIF contains forward-looking information and forward-looking statements, within the meaning of applicable Canadian securities legislation, (collectively, “forward-looking statements”), which reflect management's expectations regarding the Corporation's future growth, results from operations (including, without limitation, future production and capital expenditures), performance (both operational and financial) and business prospects, future business plans and opportunities. Wherever possible, words such as “predicts”, “projects”, “targets”, “plans”, “expects”, “does not expect”, “budget”, “scheduled”, “estimates”, “forecasts”, “anticipate” or “does not anticipate”, “believe”, “intend” and similar expressions or statements that certain actions, events or results “may”, “could”, “would”, “might” or “will” be taken, occur or be achieved, or the negative or grammatical variation thereof or other variations thereof, or comparable terminology have been used to identify forward-looking statements. These forward-looking statements include, among other things, statements relating to:

- the Company’s plans to develop, obtain regulatory approval for and commercialize its lead product candidates;
- the Company’s ability to conduct successful clinical trials for its product candidates;
- the perceived benefits of the Company’s product candidates over other treatments for infectious diseases;
- the Company’s expectations regarding its revenue, expenses and research and development operations;
- the Company’s anticipated cash needs and its needs for additional financing;
- the Company’s intention to grow the business and its operations;
- the potential size of markets for the Company’s product candidates;
- the Company’s ability to partner with other pharmaceutical companies to develop, obtain regulatory approval and commercialize its products candidates;
- expectations regarding regulatory requirements and developments for its product candidates;
- the Company’s competitive position and the regulatory environment in which the Company operates;
- the Company’s expected business objectives for the next twelve months;
- the Company’s plans with respect to the payment of dividends;

- the Company's ability to obtain additional funds through the sale of equity or debt commitments; and
- the ability of the Company's products to access markets.

Forward-looking statements are based on certain assumptions and analyses made by the Company in light of the Company's experience and perception of historical trends, current conditions and expected future developments and other factors it believes are appropriate and are subject to risks and uncertainties. In making the forward-looking statements included in this AIF, the Company has made various material assumptions, including but not limited to, the following: (i) obtaining the necessary regulatory approvals; (ii) that regulatory requirements will be maintained; (iii) general business and economic conditions; (iv) the Company's ability to successfully execute its plans and intentions; (v) the availability of financing on reasonable terms; (vi) the Company's ability to attract and retain skilled staff; (vii) market competition; (viii) the products and technology offered by the Company's competitors; (ix) that the Company's current good relationships with its suppliers, service providers and other third parties will be maintained; and (x) the efficacy of its products candidates and the success of clinical trials. Although the Company believes that the assumptions underlying these statements are reasonable, they may prove to be incorrect, and the Company cannot assure that actual results will be consistent with these forward-looking statements. Given these risks, uncertainties and assumptions, investors should not place undue reliance on these forward-looking statements. Whether actual results, performance or achievements will conform to the Company's expectations and predictions is subject to a number of known and unknown risks, uncertainties, assumptions and other factors, including those listed under "Risk Factors", which include:

- the Company expects to have negative cash flow for the foreseeable future;
- whether the Company can continue as a going concern;
- the Company is a research and development stage company with little operating history, a history of losses and the Company cannot assure profitability;
- the Company may not be successful in its efforts to identify, license or discover additional product candidates;
- none of the Company's current product candidates has to date received regulatory approval for their intended commercial sale;
- failure to follow regulatory requirements;
- additional financing needs;
- risk related to intellectual property rights;
- pre-clinical and clinical trials, including reliance on third parties to conduct same;
- pre-clinical and clinical trials will be lengthy and expensive;
- the Company may not be able to effectively manage its growth and operations, which could materially and adversely affect its business;
- the Company faces product liability exposure, which, if not covered by insurance, could result in significant financial liability;
- the Company may be required to suspend or discontinue clinical trials because of adverse side effects or other safety risks that could preclude approval of its drug candidates;
- in light of the Company's current resources and limited experience, it may need to establish successful third-party relationships to successfully commercialize its future product candidates;
- rapid technological change;
- the Company's ability to protect and enforce intellectual property rights;

- the Company may become subject to litigation, including for possible product liability claims, which may have a material adverse effect on the Company's reputation, business, prospects results from operations and financial condition;
- there may be larger, better financed companies which may become competition for the Company;
- the Company's officers and directors may be engaged in a range of business activities resulting in conflicts of interest;
- the Company does not anticipate paying cash dividends;
- the Company cannot assure you that a market will continue to develop or exist for the Common Shares and or what the market price of the Common Shares will be;
- the ability of the Company to obtain any necessary permits and licenses;
- the Company may be unable to obtain insurance;
- the market price of the Company's common shares may be subject to wide price fluctuations;
- the lack of product for commercialization;
- the lack of experience of the Company/management in marketing, selling, and distribution products;
- risks associated with future acquisitions;
- difficulty to forecast product demand;
- management conflicts of interest; and
- global economy risk.

If any of these risks or uncertainties materialize, or if assumptions underlying the forward-looking statements prove incorrect, actual results might vary materially from those anticipated in those forward-looking statements. The assumptions referred to above and described in greater detail under "Risk Factors" should be considered carefully by readers.

The Company's forward-looking statements are based on the reasonable beliefs, expectations and opinions of management on the date of this AIF (or as of the date they are otherwise stated to be made). Although the Company has attempted to identify important factors that could cause actual results to differ materially from those contained in forward-looking statements, there may be other factors that cause results not to be as anticipated, estimated or intended. There is no assurance that such statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on forward-looking statements. We do not undertake to update or revise any forward-looking statements, except as, and to the extent required by, applicable securities laws in Canada.

All of the forward-looking statements contained in this AIF are expressly qualified by the foregoing cautionary statements.

## CORPORATE STRUCTURE

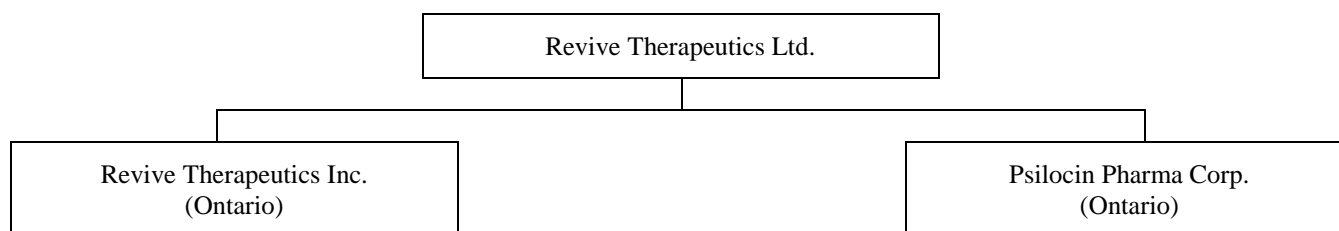
### *Name, Address and Incorporation*

Revive was incorporated pursuant to the provisions of the *Business Corporations Act* (Ontario) (“OBCA”) on March 27, 2012 under the name Mercury Capital II Limited and completed its initial public offering as a capital pool company on July 9, 2013. On December 30, 2013, Revive acquired all of the issued and outstanding securities in the capital of Revive Therapeutics Inc. (“PrivCo”) (the “Acquisition”). Upon completion of the Acquisition, Revive’s articles of incorporation were amended to change its name to “Revive Therapeutics Ltd.”

Revive’s head and principal office is located at 82 Richmond Street East, Toronto, Ontario M5C 1P1. The common shares of the Company (the “**Common Shares**”) are listed and posted for trading on the Canadian Securities Exchange (the “CSE”) under the symbol “RVV”.

### *Intercorporate Relationships*

As of June 30, 2020, its most recent financial year end, Revive conducted its business principally through the following subsidiary companies, all of which are wholly owned by Revive:



## GENERAL DEVELOPMENT OF THE BUSINESS

Revive is a life sciences company focused on the research and development of therapeutics for infectious diseases and rare disorders, and it is prioritizing drug development efforts to take advantage of several regulatory incentives awarded by the United States Food and Drug Administration (“FDA”) such as Orphan Drug, Fast Track, Breakthrough Therapy and Rare Pediatric Disease designations. Currently, the Company is exploring the use of Bucillamine for the potential treatment of infectious diseases, with an initial focus on severe influenza strains including COVID-19. Revive is also advancing the development of Psilocybin-based therapeutics in various diseases and disorders.

### **Three Year History**

#### *Business Developments related to Bucillamine during the Last Three Financial Years*

The Company’s original efforts were initially focused on the development of the drug Bucillamine for the potential treatment of cystinuria (“**REV-004**”) and acute gout flares (“**REV-002**”). Recently, the Company began exploring the use of Bucillamine as a potential novel treatment for infectious diseases including influenza and the coronavirus disease.

Below is an overview of the Company’s business developments in relation to the drug Bucillamine during the last three financial years.

With respect to the Company’s REV-004 program, the FDA granted the Company orphan drug designation for the use of Bucillamine in the treatment of cystinuria. As result, the Company submitted an investigational new drug application (“**IND**”) with the FDA to conduct a Phase II-A clinical study for the use of Bucillamine for the treatment of cystinuria. On July 6, 2016, the Company announced that the FDA had accepted its IND. The Phase II-A clinical trial was a multi-center, dose escalation trial focused on assessing the safety and effectiveness of Bucillamine on urinary cystine excretion and cystine capacity in patients with cystinuria. The primary outcome measures were the incidence of treatment-emergent adverse events along with secondary outcome measuring 24-hour urine cysteine excretion and 24-hour urine cystine capacity. The Company initiated the U.S. Phase II-A clinical study in February 2017. The Company initially sought out a development and commercialization partner to advance the REV-004 program; however, the Company has decided to halt the clinical study and commence closing study procedures as it focuses its attention on the research, development and commercialization of Bucillamine for infectious

diseases, and novel cannabinoid and psilocybin based research. See “*Regulatory Overview - U.S. Government Regulation*” for a description of the FDA’s Orphan Drug Designation and Clinical Trials process.

With respect to the Company’s REV-002 program, in November 2014, the FDA accepted the Company’s IND application to conduct a Phase II-A clinical study for REV-002 for the treatment of acute gout flares. The Company completed the Phase II-A clinical study in patients with acute gout flares in the U.S. and is in the process of closing out the study. On December 1, 2015, the Company announced positive final results from its Phase II-A clinical study of REV-002. The final primary endpoint results were reported for 74 subjects that had completed the seven-day treatment period. In February 2016, the Company received positive feedback from the FDA with respect to the Company’s proposed Phase II-B clinical study for acute gout flares, and based on this feedback the Company submitted a Phase II-B protocol to the FDA in the first half of 2016. The Company obtained approval to conduct a Phase II-B clinical study in the U.S. The Company did not intend to independently conduct Phase II-B trials, and initially sought pharmaceutical development and commercial partners for the continued development of REV-002; however the Company has since shifted its attention away from the development of the REV-002 program as it focuses its attention on the research, development and commercialization of Bucillamine for infectious diseases, and novel cannabinoid and psilocybin based research.

#### Business Developments related to Bucillamine Subsequent to the Financial Year Ended June 30, 2019

In March 2020, the Company announced that it was exploring the use of the drug Bucillamine as a potential novel treatment for infectious diseases including influenza and the coronavirus disease (“**COVID-19**”). The Company applied for a provisional patent with the U.S. Patent and Trademark Office entitled “Use of Bucillamine in the Treatment of Infectious Diseases” (Serial No. 62/991,996).

Preclinical and clinical studies have demonstrated that reactive oxygen species contribute to the destruction and programmed cell death of pulmonary epithelial cells.<sup>1</sup> N-acetyl-cysteine (NAC) has been shown to significantly attenuate clinical symptoms in respiratory viral infections in animals and humans, primarily via donation of thiols to increase antioxidant activity of cellular glutathione.<sup>4,7</sup> In addition, it was found that thiol-based drugs decrease binding of SARS-CoV-2 spike protein to its receptor, decrease the entry efficiency of SARS-CoV-2 spike pseudotyped virus, and inhibit SARS-CoV-2 live virus infection.<sup>6</sup>

Bucillamine (N-(mercapto-2-methylpropionyl)-l-cysteine) has a well-known safety profile and is prescribed in the treatment of rheumatoid arthritis in Japan and South Korea for over 30 years. Bucillamine, a cysteine derivative with two thiol groups, has been shown to be 16 times more potent as a thiol donor in vivo than NAC.<sup>7</sup> The drug is non-toxic with high cellular permeability. The basis of the clinical study will analyze if Bucillamine has the potential, via increasing glutathione activity and other antioxidant and anti-inflammatory activity, to lessen the destructive consequences of SARS-CoV2 infection in the lungs and attenuate the clinical course of COVID-19.

In April 2020, Revive filed its Pre-Investigational New Drug (“pre-IND”) meeting request with the FDA for Bucillamine in the treatment of COVID-19. The Company is relying on its previous FDA IND submissions of Bucillamine to expedite communications and obtain FDA acceptance to proceed to a phase 2 clinical study. The Company has previously been granted Phase 2 study approval for the treatment of gout and cystinuria with Bucillamine. Revive, along with the assistance of Pharm-Olam, LLC, began finalizing the clinical study protocol to advance to a Phase 2 clinical trial in the U.S. The proposed Phase 2 clinical study contemplates a multi-center, randomized, double-blind, placebo controlled, clinical study of Bucillamine in patients with mild to moderate symptoms. The proposed objectives of the study are to evaluate disease course in patients receiving Bucillamine therapy compared to a placebo, the safety of Bucillamine therapy when administered up to 14 days, and the time to clinical improvement in patients with symptoms receiving Bucillamine compared with a placebo.

Based on the Company’s pre-IND meeting request, the FDA recommended that the Company proceed directly into a Phase 3 confirmatory clinical trial (“Phase 3 study”) to evaluate Bucillamine for the treatment of patients with mild-moderate COVID-19 due to the SARS-CoV-2 infection in order to ensure expeditious evaluation of the safety and efficacy of Bucillamine

In addition to its recommendation, the FDA provided valuable guidance on study design and outcome measures for the Phase 3 study. Importantly, the FDA agreed that Revive could rely on its data included in its previous IND with Bucillamine for gout to support the COVID-19 Phase 3 study and, therefore, the Company did not have to perform any Phase 1 or Phase 2 clinical studies. The Company, along with its CDO, Pharm-Olam, LLC, and its clinical development team led by Dr. Kelly McKee, Jr., MD, MPH, Chief Scientific Officer consultant and Dr. Onesmo Mpanju, PhD, Regulatory Affairs consultant, are actively incorporating the pre-IND meeting guidance and preparing a package for submission to the FDA.

The Phase 3 study will be an adaptive design titled, “A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study of Bucillamine or Placebo in Patients with Mild-Moderate COVID-19”. Symptomatic patients will initially be randomized 1:1:1 to receive Bucillamine 300 mg/day, Bucillamine 600 mg/day, or placebo. The Phase 3 study will enroll a minimum of 210 patients, then a single Bucillamine dose is selected and a go/no-go decision is made. Patients will then be randomized 2:1 to the selected Bucillamine dose and placebo. Interim analyses will occur every 100 subjects up to the maximum sample size of 800 people. An independent data safety monitoring board (“DSMB”) will actively monitor interim data for the ongoing safety of patients. The primary objective of the Phase 3 study is to compare frequency of hospitalization and mortality in patients with mild moderate COVID-19 receiving Bucillamine therapy with those receiving placebo. The primary endpoint is a 3-level ordinal scale of a patient’s worst outcome between randomization and day 28. The levels of the ordinal outcome are 1) death, 2) alive and hospitalized, and 3) alive and not hospitalized. Secondary objectives will aim to evaluate the safety of Bucillamine therapy at low (300 mg/day) and high (600 mg/day) dose levels when administered up to 14 days; to compare disease course in patients with mild-moderate COVID-19 receiving Bucillamine therapy with those receiving placebo; to evaluate time to clinical improvement in patients with COVID-19 receiving low- and high-dose Bucillamine compared with placebo; and to assess impact of Bucillamine therapy on supplemental oxygen needs of patients with COVID-19. In addition, an exploratory objective will be to evaluate the effects of Bucillamine on viral clearance from nasal swabs in patients with COVID-19. The Company is not making any express or implied claims that its product has the ability to eliminate or cure COVID-19 (or SARS2 Coronavirus) at this time.

In June 2020, Revive met with Health Canada in a Pre-Clinical Trial Application (“**Pre-CTA**”) meeting to evaluate the potential of a clinical study of Bucillamine in the treatment of patients with mild-moderate COVID-19 due to the SARS-CoV-2 infection in Canada.

The Pre-CTA meeting provided an opportunity for Revive to discuss Bucillamine’s scientific rationale of its potential use in the treatment of COVID-19 infections, Chemistry, Manufacturing and Controls, non-clinical and clinical safety information, and clinical trial design. Health Canada provided valuable guidance on the proposed clinical study design and information required for the submission of a complete CTA package.

#### *Business Developments related to Cannabinoid-based Products during the Last Three Financial Years*

Since January 2017, the Company has been focused on the research, development and commercialization of novel cannabinoid-based products. Below is an overview of the Company’s business developments with respect to cannabinoids over the last three financial years.

In February 2017, the Company announced that it was expanding its product pipeline through the development of cannabinoid-based therapeutics targeting liver diseases. The Company has announced a number of agreements relating to this expansion of its product pipeline, including the following:

- In September 2017, the Company, through Revive Therapeutics Inc., and South Carolina Research Foundation (“**SCRF**”) entered into a license agreement (the “**SCRF License Agreement**”), under which Revive Inc. was granted an exclusive license by SCRF to develop and commercialize certain intellectual property protected by a portfolio of patents based on cannabinoid-based therapeutics, such as cannabidiol (“**CBD**”), in the treatment of liver diseases. See “Products Under Research and Development Programs in Liver Diseases”.
- In October 2017, the Company, through Revive Therapeutics Inc., entered into a research collaboration with Sanyal Biotechnology LLC (“**SanyalBio**”) focused on advancing cannabinoids for the potential treatment of liver diseases. This research collaboration led the Company to announce on January 30, 2018 the advancement of a research program to evaluate CBD in the treatment of autoimmune hepatitis (“**AIH**”), a rare liver disease. This research program is also overseen by SanyalBio.
- In March 2018, the Company and Ehave, Inc., a healthcare company dedicated to empowering the mental health community with next-generation digital solutions, announced that they had entered into a collaboration agreement to enable enhanced patient and clinical research data management for Revive’s research initiatives involving medical cannabis for the treatment of liver diseases.
- In June 2018, the Company, through Revive Therapeutics Inc., entered into a supply agreement and a collaboration agreement for medical cannabis products and therapies (the “**WeedMD Agreements**”) with WeedMD Inc. (“**WeedMD**”), a federally-licensed producer and distributor of medical cannabis. Under the WeedMD Agreements, WeedMD will supply Revive Inc. with CBD for the research program evaluating CBD in the treatment of liver disease,



specifically non-alcoholic steatohepatitis and AIH. WeedMD will support the Company's research, development and potential commercialization of CBD in the treatment of liver disease. Additionally, Revive and WeedMD agreed to identify opportunities for developing and commercializing medical cannabis products and therapies for potential collaboration in other treatments.

The Company's efforts to develop cannabinoid-based therapeutics targeting liver diseases resulted in the Company announcing in June, 2018 that it had been granted Orphan Drug Designation from the FDA for the use of CBD in the treatment of AIH. See "*Regulatory Overview – U.S. Government Regulation*" for a description of the FDA's orphan drug designation.

In addition to focusing on the development of cannabinoid-based therapeutics targeting liver diseases, during 2017 and 2018 the Company, through Revive Inc., engaged and successfully completed a research program with the University of Wisconsin-Madison (the "University of Wisconsin-Madison Research Program") focused on the development of a technology to potentially deliver cannabinoids via the topical route. The research project evaluated tannin-chitosan based hydrogel formulations in combination with synthetic cannabidiol in anti-inflammatory and permeability models. The results demonstrated a new and stable formulation of the tannin-chitosan composites and synthetic cannabidiol (the "Formulation"). The Formulation shown to attenuate LPS-induced macrophage activation in a dose-response manner, showing a reduction for inducible nitric oxide synthase (iNOS), as well as an increase on intracellular production of tumor necrosis factor alpha (TNF- $\alpha$ ) as the concentration of CBD is increased. Thus, the Formulation exhibited anti-inflammatory properties and suggested that the tannin-chitosan composites have anti-inflammatory activity that may complement synthetic cannabidiol. Also, the Formulation successfully demonstrated that the addition of tannin-chitosan composite to synthetic cannabidiol directly influenced its topical diffusion properties and the tannin-chitosan composite was able to reduce synthetic cannabidiol permeability through the simulated skin membrane, thus increasing the time for its availability and enabling the potential to be developed as a controlled or sustained release delivery system that may lead to single-dose treatments. The successful completion of the University of Wisconsin-Madison Research Program led the Company to announce on April 30, 2018 that it had, through Revive Inc., entered into an exclusive worldwide license agreement with the Wisconsin Alumni Research Foundation ("WARF") for the commercialization of the Company's cannabinoid delivery technology (the "WARF License Agreement"). Under the terms of the WARF License Agreement, the Company gained exclusive worldwide rights to intellectual property for the development and commercialization of cannabinoid-based products for therapeutic and/or prophylactic purposes delivered via topical, subcutaneous, buccal-mucosal or oral applications. See "Exclusive Worldwide License Agreement with WARF".

The Company also entered into other agreements relating to its new focus on the research, development and commercialization of novel cannabinoid-based products. These agreements include the following:

- In November 2017, the Company, through Revive Inc., entered into a license and development agreement with Nexalogy Environics Inc., (a wholly owned subsidiary of Datamatrix AI Limited) to develop the actionable intelligence component in Revive's proprietary patient-focused program enabled by blockchain technology dedicated to the medical cannabis industry. This agreement was completed in May 2018.
- In December 2017, the Company, through Revive Inc., entered into a collaboration agreement with Chemi Pharmaceutical Inc., a licensed dealer for cannabis pursuant to the *Controlled Drugs and Substances Act* under Health Canada and in possession of a laboratory approved by the FDA. As of the date of this AIF, no activities have been performed by either party under this agreement.

#### *Other Business Developments during the Last Three Financial Years*

On August 18, 2016, the Company completed a non-brokered private placement of units for gross proceeds of \$1,500,000 (the "**August 2016 Offering**"). Pursuant to the August 2016 Offering, the Company issued 15,000,000 units at \$0.10 per unit. Each unit consisted of one common share and one-half of one common share purchase warrant. The Company paid \$113,765 in cash finder's fees and other transaction costs of which, \$90,692 was allocated to share capital and \$23,073 was allocated to the common share purchase warrants. The Company also issued 492,450 finder's warrants to qualified arm's length finders. The finder's warrants entitled the holder to acquire one unit for \$0.10 until June 18, 2018.

In August 2018, the Company, through Revive Inc., and AXIM Biotechnologies, Inc. ("**Axim**") entered into a distribution and license agreement (the "**Axim Agreement**") related to the exclusive commercialization in Canada of Axim's CanChew™ product, a CBD-based controlled release chewing gum. The Company intends to market this product in Canada under the brand RELICANN™, which was announced by the Company on September 11, 2018. See "*Proposed buccal cannabinoid delivery technology*".

Also in August 2018, the Company announced that it had submitted an application to the FDA seeking orphan drug designation of CBD for the treatment of hepatic ischemia and reperfusion injury (“**IRI**”) during liver transplantation. Liver ischemia-reperfusion injury is a major complication of liver transplantation and is one of the leading causes for postsurgery hepatic dysfunction leading to an increased risk of postoperative morbidity and mortality. According to the United Network for Organ Sharing (“**UNOS**”) there have been 160,722 liver transplants performed between January 1, 1988 and July 30, 2018. Currently there are 13,773 individuals on the waiting list for a liver transplant. Quickly restoring blood supply of ischemic liver as soon as possible is crucial for avoiding or reducing injury from ischemia, whereas strategies used to attenuate the damage induced by reperfusion, including ischemic preconditioning, ischemic postconditioning, and machine perfusion. These strategies are expensive, sometimes hard to perform in clinical surgeries, and difficult in maintaining liver functions in the case of acute injuries. Revive believes that the immunosuppressant and anti-inflammatory protective effects of CBD may provide a novel, more beneficial strategy to attenuate the damage induced by ischemia and reperfusion during liver transplantation.

In November 2018, the FDA granted orphan drug designation for CBD in the prevention of IRI resulting from solid organ transplantation. According to the U.S. Organ Procurement and Transplantation Network, there are approximately 115,000 patients waiting for solid organ transplants in the United States, with the four most common organs transplanted being liver, kidney, heart and lung. IRI in organ transplantation can result in a higher incidence of acute and chronic rejection, as well as long-term morbidity and mortality. With the shortage of organs and expensive medical strategies, it is clear that therapies need to be researched to optimize the quality of the organs that are available and to attenuate injury to transplanted organs. Revive believes that the immunosuppressant and anti-inflammatory protective effects of CBD may provide a novel, more beneficial strategy to attenuate the damage induced by ischemia and reperfusion during solid organ transplantation See “*Regulatory Overview – U.S. Government Regulation*” for a description of the FDA’s Orphan Drug Designation.

On February 5, 2019, the Company completed the first tranche of a non-brokered private placement for a total of 10,960,000 units, at a price of \$0.10 per unit for gross proceeds of \$1,096,000 (the “**February Offering**”). Each unit consisted of one common share of Revive and one whole common share purchase warrant. Each common share purchase warrant entitles the holder to acquire one common share for \$0.15 per common share for 24 months following closing of the February Offering.

In conjunction with the completion of the February Offering, Revive entered into a series of agreements (collectively the “**HHL Transactions**”) with Herman Holdings Limited (“**HHL**”). The HHL Transactions received approval of the TSX-V and consist of the following:

- (1) Revive and HHL entered into a binding letter of intent (“**JV LOI**”) pursuant to which Revive and HHL will establish and hold interests on a 60%/40% basis in a new corporation (“**JVCo**”) with a business in extraction and marketing of cannabis oils and which, pursuant to the terms of the JV LOI and in accordance with applicable laws and the policies of the TSX-V, will pursue an application for a Standard Processing License under the *Cannabis Act* (Canada).

Pursuant to the terms of the JV LOI, each of Revive and HHL will have the right to appoint one member of the board of the JVCo and shall have the right to appoint the third director of JVCo jointly. The JV LOI also provides that upon entering into the definitive joint venture agreement, HHL will have the right to appoint one director to the board of directors of Revive (the “**Board**”) and to nominate one member of the Board at each shareholder meeting thereafter for as long as the definitive agreement is in effect.

The JVCo was never incorporated and Revive and HHL did not pursue the JVCo.

- (2) In connection with the closing of the first tranche of the February Offering, Revive acquired an aggregate of 1,820,000 common shares of HHL at a price of \$0.30 per common share of HHL for gross proceeds of \$546,000 representing 4.1% of the issued and outstanding HHL shares. Pursuant to the subscription agreement for common shares of HHL, in the event that HHL undertakes business in the United States or another jurisdiction which is unacceptable to the TSX-V, Revive will be required to provide a notice to the TSX-V for further review.
- (3) The Company entered into a supply agreement with a wholly-owned subsidiary of Richmond Cannabis Co. (“**Richmond**”), a partner of HHL, pursuant to which Richmond undertakes to supply, in accordance with applicable laws and upon receipt of all required licenses, the cannabis required for the proposed extraction operations of Revive and the JVCo.

On February 11, 2019, the Company completed the second tranche of the February Offering. The second tranche of the February Offering consisted of the sale of 3,050,000 units, for the aggregate gross proceeds of both tranches of the February

Offering of \$1,401,000. In connection with the closing of the second tranche of the February Offering, Revive acquired an additional 680,000 common shares of HHL at a price of \$0.30 per common share of HHL for gross proceeds of \$204,000. As a result, the Company holds 2,500,000 HHL shares in the aggregate or approximately 6.7% of the issued and outstanding HHL shares.

In April 2019, the Company was granted United States Patent No. 10,104,888, titled "Tannin-chitosan composites," by the United States Patent and Trademark Office. This patent expands Revive's coverage for the delivery of cannabinoids in various delivery routes. Revive has rights to the patent through an exclusive worldwide license agreement with the Wisconsin Alumni Research Foundation that covers cannabinoids delivered via the buccal-mucosa (the inner lining of the lips and cheeks, where cannabinoids absorb more readily into the bloodstream), topical, oral, and subcutaneous applications. The patent is anticipated to expire on September 3, 2030.

In June 2019, Revive announced plans to establish a cannabis product derivative manufacturing and development facility and it has entered into a definitive lease and purchase option agreement to a 12,000 sq. ft. facility in Mississauga, Ontario (the "Mississauga Facility") with an option to acquire 100% interest in the Mississauga Facility, as well as the option to expand into a 50,000 sq. ft. facility, at the Company's discretion, in Bowmanville, Ontario (the "Bowmanville Facility"). The Company has decided to not pursue the cannabis product derivative manufacturing and development facility.

#### *Business Developments Subsequent to the Financial Year Ended June 30, 2019*

Since its June 30, 2019 financial year end, the Company has continued its focus on the research, development and commercialization of novel cannabinoid-based products as well the development of the drug Bucillamine for the potential treatment of infectious diseases, with an initial focus on severe influenza strains including COVID-19.

In July 2019, Revive received approval to list its common shares for trading through the facilities of the Canadian Securities Exchange (the "CSE"). The Company voluntarily delisted its common shares from the TSX Venture Exchange after the market close on July 22, 2019 and commenced trading on the CSE at the market opening on July 23, 2019.

In November 2019, Revive entered into a non-binding letter of intent (the "LOI") to acquire Greeninsightz Limited ("Greeninsightz"), an artificial intelligence data software company focused on the cannabis sector, by amalgamation or other form of business combination. In addition, the Company engaged Hampton Securities Limited, as sole lead agent, in connection with a private placement offering, on a "commercially reasonable efforts" basis, of up to 40,000,000 subscription receipts of the Company (the "Subscription Receipts") at a price of \$0.05 per Subscription Receipt for gross proceeds of up to \$2,000,000 (the "Offering"). The Company terminated the LOI in January, 2020.

In December 2019, Mr. Michael Frank was elected Chairman of the Board and appointed Chief Executive Officer of the Company. Mr. Craig Leon and Mr. Fabio Chianelli, previously Chief Executive Officer and President respectively, resigned as officers of the Company. Furthermore, Mr. Leon, Mr. Chianelli and Mr. Carlo Sansalone have stepped down from the board of directors, and Mr. Christian Scovenna and Mr. Andrew Lindzon were elected as new members of the board of directors.

In February 2020, Revive issued 210,000 secured convertible debenture units (the "Debenture Units") to arm's length parties for aggregate gross proceeds of \$210,000. Each Debenture Unit consists of one (1) 12% secured convertible debenture (the "Convertible Debentures") maturing three (3) years from the date of issuance and 20 common share purchase warrants of Revive (the "Warrants"). Each Warrant shall entitle the holder thereof to purchase one common share in the capital of Revive (each, a "Common Share") at an exercise price of \$0.07 at any time up to February 5, 2023. The Convertible Debentures will have a maturity 36 months from the date of issuance (the "Maturity Date") and shall bear interest at a rate of 12% per annum from the date of issue. Interest will accrue and be payable on the Maturity Date. The holder of the Convertible Debentures shall have the right to demand immediate payment of the Convertible Debentures, together with all accrued interest thereon, provided that such demand cannot be made prior to June 6, 2020. The principal amount of each Convertible Debenture shall be convertible, for no additional consideration, into Common Shares at the option of the holder at any time prior to the close of business on the Maturity Date at a conversion price equal to \$0.05 (the "Conversion Price") per Common Share. The Convertible Debenture, along with all accrued interest was converted into an aggregate of 4,368,000 common shares in June 2020.

Additionally in February 2020, Revive entered into a supply and collaboration agreement (the "Agreement") with Red Light Holland Financing Inc. ("Red Light"). Pursuant to the Agreement Red Light will sell to Revive a consistent strain of truffles for the sole purpose of Revive undertaking research and development on the suitability and implementation of its novel cannabinoid delivery technology with respect to the truffles and its extracts. Red Light has also agreed to, upon request, provide

Revive with any information, studies, papers and other information it may have pertaining to the truffles which may be deemed to be beneficial to Revive for undertaking the research and development. In addition, as a condition of the Agreement, Revive has agreed to subscribe for 2,500,000 subscription receipts (the "Subscription Receipts") of Red Light at a price of \$0.06 per Subscription Receipt for an aggregate consideration of \$150,000. Each Subscription Receipt shall entitle Revive, upon conversion and with any additional consideration, to acquire one common share in the capital of Red Light. In consideration for the Subscription Receipts, Revive will issue to Red Light an aggregate of 3,000,000 common shares in the capital of Revive at a price of \$0.05 per share for aggregate consideration of \$150,000.

In March 2020, Revive acquired all of the issued and outstanding securities in the capital of Psilocin Pharma Corp. ("Psilocin"), a specialty psychedelic sciences company focused on the development of Psilocybin-based therapeutics for significant unmet medical needs including rare and orphan indications.

Pursuant to the terms of a share exchange agreement dated March 4, 2020, Revive acquired all of the issued and outstanding securities of Psilocin for an aggregate purchase price of \$2.75 million (the "Purchase Price"). The Purchase Price was satisfied through the issuance of an aggregate of 55 million common shares in the capital of Revive at a deemed price of \$0.05 per share.

Psilocin has developed patent-pending formulation and production solutions for the active compound Psilocybin. The process encompassed with its intellectual property cover methods of production of Psilocybin-based formulations. Psilocin has developed formulations to date which include the Hydroxy Line. The line will include PSY-0.1 -Capsules- PSY-0.2 – Sublingual Spray- PSY-0.3 -Gel Cap- PSY-0.4/0.5 -Effervescent Tablets-and PSY-0.6 -Breath Strips. The precisely dosed formulations will work with both natural and synthetically derived Psilocybin which will be targeted for clinical research and subject to FDA approval in the treatment of depression, anxiety, bi-polar disorder, bulimia and anorexia nervosa, and a number of other diseases. Psilocin's range of products have been engineered to work synergistically with the body's own natural pathways of absorption while offering a contemporary approach to consumption.

Psilocin has filed key provisional patent applications with the U.S. Patent and Trademark Office that cover methods of production of Psilocybin-based formulations. This includes sublingual sprays, effervescent tablets, hard-shell capsules, sublingual and transmucosal delivery systems (i.e. gum drops, oral strips, dosing pens). Furthermore, Psilocin has a patentpending portfolio that includes Psilocybin extraction and crystallization methodologies. Specifically, the Psilocin patent applications relate to the following:

- Solid Oral Pharmaceutical Compositions, United States Provisional Application Serial No. 62/985,052 – Psilocybin effervescent and psilocybin tablet designed to be placed under the tongue or dissolved in water. Allowing for improved taste and controlled release profiles.
- Pharmaceutical Capsule Compositions, United States Provisional Application Serial No. 62/985,070 - Psilocybin hardshell capsules containing dry, powdered ingredients in 2-piece capsules. Allowing for contemporary consumption familiar to the user (Gelatin and vegetarian enclosure options in addition to unique nutrient delivery combination options).
- Pharmaceutical Gumdrops Compositions, United States Provisional Application Serial No. 62/985,084 - Psilocybin gumdrops for improved administration of compounds. Offers unique delivery methods for fat and water soluble options.
- Thin-Film Pharmaceutical Delivery System and Formulations, United States Provisional Application Serial No.62/985,098 - Psilocybin oral strips and psilocybin transmucosal delivery system. Proprietary oral fast-dissolving drug delivery system rapidly releases through the buccal pathway.
- Pharmaceutical Formulations and Methods for Sublingual and Buccal Administration, United States Provisional Application Serial No. 62/984,590 - Formulation for spray/pump/dosing pen.
- Methods for the Extraction and Crystallization of Psilocybin, United States Provisional Application Serial No. 62/985,360 - Psilocybin extraction and psilocybin re-crystallization method patent allows for the extraction of Psilocybin from raw form of magic mushrooms or magic truffles. Psilocin's proprietary extraction process allows for the extraction of whole fungi extract with the option to selectively pull out pure Psilocybin Isolate in the downstream process.

Revive intends to take advantage of a number of regulatory incentives awarded by the FDA, such as orphan drug, fast track, breakthrough therapy and rare pediatric disease designations, and will also categorize opportunities that have FDA priority review voucher potential, which historically have been valued between \$67.5 and \$350 million. This strategy is complementary to Revive's cannabinoid-based pharmaceutical portfolio, specifically clinical development of Cannabidiol in the treatment of Autoimmune Hepatitis, which already has FDA orphan drug designation. Revive is currently in the process of preparing an investigational new drug application for submission to the FDA.

In addition, in March 2020, Revive completed the first tranche of a brokered private placement for a total of 33,535,000 units (the "March Units"), at a price of \$0.05 per unit for gross proceeds of \$1,676,750 (the "March Offering"). Hampton Securities Limited acted as sole lead agent (the "Agent") in connection with the March Offering.

Each March Unit consists of one common share ("Share") in the capital of the Company and one common share purchase warrant ("March Warrant"). Each March Warrant entitles the holder thereof to acquire one common share of the Company (each a "March Warrant Share") at a price of \$0.07 per March Warrant Share at any time until March 18, 2023. Pursuant to the March Offering, Revive paid the Agent a cash commission of \$150,907.50, a corporate finance fee of \$22,600 and issued the Agent and its sub-agents 3,018,150 non-transferable broker warrants (the "March Broker Warrants"). Each March Broker Warrant entitles the Agent to purchase one unit of the Company (each a "March Compensation Unit") at the price of \$0.05 per March Compensation Unit at any time until March 18, 2022. Each March Compensation Unit is comprised of one common share in the capital of the Company and one common share purchase warrant (each a "March Compensation Unit Warrant"). Each March Compensation Unit Warrant entitles the holder thereof to purchase one common share in the capital of the Company (each a "March Compensation Warrant Share") at a price of \$0.07 per March Compensation Warrant Share at any time until March 18, 2023.

In March 202, Revive appointed Dr. David Boulware, MD, MPH, CTropMed, FIDSA, as its Scientific Advisor to guide on the Company's current and future clinical programs including its research and development strategy for infectious diseases, including the coronavirus disease ("COVID-19").

Dr. Boulware is an infectious disease physician-scientist and Professor of Medicine, Division of Infectious Diseases and International Medicine at The University of Minnesota. Dr. Boulware is currently the Principal Investigator of a globally recognized COVID-19 clinical trial to determine if post-exposure prophylaxis with hydroxychloroquine can prevent progression development of symptomatic COVID-19 disease after known exposure to the SARS-CoV2 virus (ClinicalTrials.gov Identifier: NCT04308668). His primary research interests are in meningitis in resource-limited areas including diagnosis, prevention, treatment, and quality improvement initiatives incorporating cost-effectiveness analyses in order to translate knowledge into improved care. Dr. Boulware's current research is focused on improving the clinical outcomes of HIV-infected persons with cryptococcal meningitis and TB meningitis. Dr. Boulware has active research collaborations in Uganda, South Africa, and Ethiopia leading a multidisciplinary, international research team. He serves on US and WHO panels for cryptococcal meningitis and WHO panels for advanced HIV disease.

Additionally, Revive retained Pharm-Olam, LLC, a private company with proven clinical experience in infectious diseases completing over 100 clinical studies in approximately 19,000 patients at over 2,000 clinical sites, to serve as the Company's Contract Research Organization ("CRO") to advance the future clinical study for Bucillamine in the treatment of infectious diseases, including COVID-19.

Pharm-Olam is a midsized CRO that offers flexible, innovative, and highly personalized clinical solutions to pharmaceutical, biotechnology, and life science companies. It is well-known for producing quality results with reduced risk, costs, and timelines in challenging international trials. It provides full-service solutions, data protection services, and expertise in oncology, infectious diseases and vaccines, rare and orphan diseases, pediatrics, and general medicine.

Revive also added Dr. Kelly McKee, Jr., MD, MPH as Chief Scientific Officer consultant and Dr. Onesmo Mpanju, PhD as Regulatory Affairs consultant to the Company's clinical development team.

Dr. McKee is currently Senior Scientific and Medical Advisor for Pharm-Olam. Previously, Dr. McKee served as Pharm-Olam's Chief Medical Officer, and as Vice President, Vaccines and Public Health, in the Infectious Diseases and Vaccines Center of Excellence at IQVIA (previously QuintilesIMS). He brings over 30 years of experience in research and development from the bench to the bedside, with specific expertise in vaccines, emerging diseases, biodefense, respiratory viral infections, and sexually transmitted infections. His progressive clinical research experience began in 1981 at Fort Detrick, Frederick, Md., United States, where he served as a research virologist, immunologist, and Head of the Dept of Clinical Investigation and Medical Division at the US Army Medical Research Institute of Infectious Diseases (USAMRIID).

Dr. Onesmo Mpanju, PhD has over 28 years of experience in biopharmaceutical R&D, including 18 years as a regulatory scientist. Previously, Dr. Mpanju was a Reviewer at the FDA, Center for Biologics Evaluation & Research. His consulting experience includes non-commercial entities such as the U.S. National Institutes of Health, US Army Medical Materiel Development Activity (USAMMDA), the Bill & Melinda Gates Foundation, and others. Dr. Mpanju holds a Ph.D. in Experimental Medicine (Infectious Diseases) from the University of British Columbia.

In April 2020, Revive retained Novotech, the largest biotech clinical research organization (“CRO”) specialist in the AsiaPacific region, to serve as the Company’s CRO to pursue future human clinical studies for Bucillamine in the treatment of infectious diseases, including COVID-19 in Asia-Pacific Countries (“APAC”).

Novotech was established in 1996 and is recognized as the leading regional full-service contract research organization in Asia-Pacific and has been instrumental in the success of over a thousand Phase I - IV clinical trials for biotechnology companies. With offices in 11 locations across the region, and site partnerships with major health institutions. Novotech provides clinical development services across all clinical trial phases and therapeutic areas including: feasibility assessments; ethics committee and regulatory submissions, data management, statistical analysis, medical monitoring, safety services, central lab services, report write-up to ICH requirements, project and vendor management. Novotech obtained the ISO 27001 certification which is the best-known standard in the ISO family providing requirements for an Information Security Management System. Together with the ISO 9001 Quality Management system, Novotech aims at the highest IT security and quality standards for patients and biotechnology companies.

In addition, in April 2020, Revive completed the second tranche of a brokered private placement for a total of 16,400,000 units (the “April Units”), at a price of \$0.05 per unit for gross proceeds of \$820,000 (the “April Offering”). Hampton Securities Limited acted as sole lead agent (the “Agent”) in connection with the April Offering.

Each April Unit consists of one common share (“Share”) in the capital of the Company and one common share purchase warrant (“April Warrant”). Each April Warrant entitles the holder thereof to acquire one common share of the Company (each an “April Warrant Share”) at a price of \$0.07 per April Warrant Share at any time until April 14, 2023. Pursuant to the April Offering, Revive paid the Agent a cash commission of \$73,800 and issued the Agent and its sub-agents 1,476,000 non-transferable broker warrants (the “April Broker Warrants”). Each April Broker Warrant entitles the Agent to purchase one unit of the Company (each an “April Compensation Unit”) at the price of \$0.05 per April Compensation Unit at any time until April 14, 2022. Each April Compensation Unit is comprised of one common share in the capital of the Company and one common share purchase warrant (each an “April Compensation Unit Warrant”). Each April Compensation Unit Warrant entitles the holder thereof to purchase one common share in the capital of the Company (each an “April Compensation Warrant Share”) at a price of \$0.07 per April Compensation Warrant Share at any time until April 14, 2023.

Also in April 2020, Revive engaged Complete Phytochemical Solutions, LLC., an internationally-recognized company specializing in unique and complex analyses and formulation development of phytochemicals, to advance the Company’s research and development initiatives of psilocybin-based products for the pharmaceutical market. Complete Phytochemical Solutions, formed as a University of Wisconsin--Madison spinoff company in 2010, is led by Christian G. Krueger as Chief Executive Officer and Jess D. Reed, PhD as Chief Scientific Officer. Both Dr. Reed and Mr. Krueger conduct translational phytochemical research and formulation development out of the Reed Research Lab at the University of Wisconsin-Madison. Dr. Reed and Mr. Krueger have recently collaborated with Revive on development initiatives using their patented tannin-chitosan composites as a delivery vehicle for cannabinoids.

Revive also entered into a sponsored research partnership agreement (“SRPA”) with the University of Wisconsin-Madison to evaluate novel formulations and drug delivery technology focused on psilocybin-based pharmaceuticals. The research program will be conducted at the Reed Research Group and will be led by Dr. Jess D. Reed, Ph.D., Professor of Animal Sciences at the University of Wisconsin-Madison. Under the agreement, Dr. Reed and his research team will evaluate psilocybin-based formulations and the patented Tannin-Chitosan composite drug delivery technology for psilocybin, in which the Company has an exclusive license with the Wisconsin Alumni Research Foundation.

Dr. Reed is a phytochemist and nutritionist that studies the effects of oligomeric polyphenols on the health of animals and humans. A main thrust of the Reed Research Group is to determine how plant polyphenols can be used in the development of new materials for use in the human and animal health, food processing and preservation, and other applications. This research effort includes the development of phytochemical methods for characterization of structure of oligomeric polyphenols and their ability to combine with other biopolymers such as chitosan. Research on the interaction between tannins and chitosan has led to the discovery of a new composite material that have antimicrobial activity and can be formed into films, foams, hydrogels

and nanoparticles that have applications in food, agriculture and health. Chitosan is a derivative of chitin that is present in the shells of shrimp, crabs, insects and other arthropods. Chitin is the second most abundant biopolymer on the earth's surface after cellulose. The Reed Research Group also carries out mechanistic studies on the effects of these biomaterials in cell culture and animal models of disease.

The drug delivery technology aims to deliver both synthetic and natural extract of psilocybin in a potential number of ways such as topical gels, creams or ointments, oral or transdermal patches, oral dosages and foams. The delivery technology is a natural, non-toxic, biodegradable and biocompatible composite that combines a tannin material, which is derived from a plant group having antibacterial, antifungal, antioxidant and wound healing properties, and a chitosan material, which is derived from the crustacean group having blood-clotting and antimicrobial properties. The delivery technology has a rapid onset of action and controlled or sustained release potential capabilities and may allow combining multiple extracts from mushrooms in one formulation. The drug delivery technology offers licensed pharmaceutical companies new product opportunities for various medical disorders.

In June 2020, Revive expanded its sponsored research partnership agreement ("SRPA") entered with the University of Wisconsin Madison to evaluate novel formulations of psilocybin and a Phase 1 clinical study investigating the therapeutic application of psilocybin for an undisclosed addiction use disorder.

The research and development work being carried out at the University of Wisconsin-Madison focuses on tannin-chitosan composites in the form of thin films, hydrogels and 3D foams. The research will include the development of composite formulations, physio-chemical characterization (e.g. tensile strength of films) of composite materials and rate of psilocybin release from composites. Final formulations will be investigated in pre-clinical and clinical studies in various diseases and disorders. The Company has identified tannin-chitosan composite thin films as the lead candidate for the development of a unique delivery platform for therapeutic doses (1-20mg) of psilocybin into the oral cavity.

In September 2020, the Company entered into a clinical trial agreement (the "CTA"), dated August 28, 2020, with the Board of Regents of the University of Wisconsin System ("UWS") to conduct a clinical study entitled, "Phase I Study of the Safety and Feasibility of Psilocybin in Adults with Methamphetamine Use Disorder." Under the terms of the CTA, the Company has an exclusive option to obtain an exclusive, worldwide, royalty-bearing commercialization license to all rights, title and interest that UWS may have or obtain in any invention that results from the clinical study.

In October 2020, the Company entered into a supply agreement (the "Agreement") with Havn Life Sciences Inc. to source naturally-derived psychedelic compounds, such as psilocybin, for use in future investigational new drug ("IND") enabling studies and clinical trials under the Food and Drug Administration ("FDA") guidelines.

In November 2020, the Company entered into an exclusive research collaboration agreement with PharmaTher Inc. to accelerate the development of psilocybin in the treatment of cancer and the discovery of novel uses of undisclosed psychedelic compounds.

In December 2020, appointed Dr. Joel Moody, MD, MPH, DTM&H, as a medical and clinical advisor to the Company to assist in the expansion of clinical studies in Canada and the clinical data analysis on the ongoing U.S. Food & Drug Administration ("FDA") Phase 3 clinical trial (the "Study") to evaluate the safety and efficacy of Bucillamine in patients with mild-moderate COVID-19.

Dr. Joel Moody has over 15 years of experience in clinical research in oncology (breast and ovarian cancer), sickle cell disease, Human T-Lymphotropic Virus, Types I and II, cholera, and tuberculosis. He brings international expert knowledge and experience in clinical and epidemiological studies. During his career, Joel has helped to launch and manage global phase I - IV clinical studies, including large scale morbid-mortality trials. Joel trained in oncology, tropical and infectious diseases, and internal medicine and completed fellowships at the Lunenfeld-Tanenbaum Research Institute in Mount Sinai Hospital/University of Toronto and the Instituto de Medicina Tropical "Alexander von Humboldt"/ Universidad Peruana Cayetano Heredia (Lima, Peru).

In December 2020, the Company entered into a non-binding letter of intent (the "LOI"), dated December 20, 2020, to acquire the full rights to PharmaTher Inc.'s intellectual property (the "Acquired Assets") pertaining to psilocybin (the "Acquisition"). The Acquired Assets will include all of the following:

- all intellectual and work property derived from PharmaTher's pre-clinical research activities in traumatic brain injury and stroke, with the aim to obtain U.S. Food and Drug Administration ("FDA") Orphan Drug Designation;

- all intellectual property portfolio covering neurological disorders, cancers and novel combinations of psilocybin and FDA approved drugs;
- all intellectual and work property derived from the study being currently undertaken by the National Health Research Institute in Taiwan; and
- key provisional patent applications with the U.S. Patent and Trademark Office, which include:
  - Psilocybin in the Treatment of Neurological Brain Injury - United States Provisional Application Serial No. 63/011,493 – Relates to pharmaceutical compositions comprising psilocybin and their use for the treatment of neurological brain injuries and migraines.
  - Use of Psilocybin in the Treatment of Cancer, United States Provisional Application Serial No. 63/113,913 – Psilocybin’s use of significant unmet medical needs for Liver Carcinoma, Melanoma, Breast Neoplasms, Kidney Neoplasms and Acute Myeloid Leukemia.
  - Psilocybin Pharmaceutical Combination Therapies, United States Provisional Application Serial No. 63/125,106 – Novel combinations of certain FDA approved drugs with psilocybin as a potential therapeutic option to reduce the side effects and improve the effectiveness of psilocybin to treat neurological disorders.

The Acquisition follows the previously announced exclusive research collaboration agreement with PharmaTher to accelerate the development of psilocybin in the treatment of cancer and the discovery of novel uses of undisclosed psychedelic compounds.

In December 2020, the Company appointed Dr. John Fahy, MD, MSc, as a Scientific and Clinical advisor to the Company to assist in the expansion and the analysis of the clinical data on the ongoing U.S. Food & Drug Administration (“FDA”) Phase 3 clinical trial (the “Study”) to evaluate the safety and efficacy of Bucillamine in patients with mild-moderate COVID-19.

Dr. John Fahy, MD, MSc is a Professor of Medicine in the Division of Pulmonary and Critical Care Medicine and the Department of Medicine at the University of California San Francisco and is a director of UCSF’s severe asthma clinic. He also cares for critically ill patients in the intensive care units and directs the UCSF Airway Clinical Research Center. His research receives funding from the National Institutes of Health and various foundations, as well as contracts from biotechnology and pharmaceutical companies in disease mechanisms of asthma, cystic fibrosis and other airway diseases. Fahy earned his medical degree at the University College Dublin. After internal medicine training in Dublin, he completed fellowship training in pulmonary and critical care medicine at UCSF. He is the Michael S. Stulbarg Endowed Chair in Pulmonary Medicine.

In January 2020, the Company entered into a sponsored research agreement and an exclusive option to license agreement with North Carolina State University (“NC State”) to develop a novel biosynthetic version of psilocybin based on a natural biosynthesis enzymatic platform developed by Dr. Gavin Williams, Professor and Researcher at NC State.

The biosynthetic platform developed by Dr. Gavin Williams provides a potential simple and efficient method for rapidly producing natural products, such as psilocybin, using an engineered enzymatic pathway in *E. coli*. Dr. Williams and his team recently developed an artificial enzymatic platform called the ‘Alcohol Dependent Hemiterpene’ pathway for construction of alkyl pyrophosphates. Here, the products of the ADH pathway will be used to generate key building blocks for psilocybin and its derivatives. The goal is to engineer *E. coli* to be a factory for psilocybin production, using a completely artificial biosynthetic logic.

### **Significant Acquisitions**

The Company did not complete any acquisitions during the financial year ended June 30, 2020, for which disclosure is required under Part 8 of National Instrument of 51-102 - *Continuous Disclosure Obligations* (“**NI 51-102**”).



## REGULATORY OVERVIEW

### Regulatory Framework in Canada

The following summary addresses the primary Canadian federal laws and regulations associated with the production and distribution of legal cannabis and related products. It does not address the laws and regulations of any other jurisdiction.

#### *Background*

On October 17, 2018, the *Cannabis Act* (Canada) and the *Cannabis Regulations* came into force, legalizing the sale of cannabis for adult recreational use. Prior to the *Cannabis Act* (Canada) and the *Cannabis Regulations* coming into force, only the sale of medical cannabis was legal and was regulated by the Access to Cannabis for Medical Purposes Regulations (“ACMPR”) made under the *Controlled Drugs and Substances Act* (Canada) (“CDSA”). The *Cannabis Act* (Canada) and the *Cannabis Regulations* replaced the CDSA and the ACMPR as the governing laws and regulations in respect of the production, sale and distribution of medical cannabis and related oil extract. Given that the *Cannabis Act* (Canada) and the *Cannabis Regulations* are very new, the impact of such regulatory changes on the Company's business is unknown. See “*Risk Factors – Changes in laws and regulations*”. The *Cannabis Act* (Canada) provides a licensing and permitting scheme for the production, importation, exportation, testing, packaging, labelling, sending, delivery, transportation, sale, possession and disposal of cannabis for non-medicinal use (i.e. adult use), to be implemented by regulations made under the *Cannabis Act* (Canada). The *Cannabis Act* (Canada) maintains separate access to cannabis for medical purposes, including providing that import and export licences and permits will only be issued in respect of cannabis for medical or scientific purposes or in respect of industrial hemp. The *Cannabis Regulations*, among other things, set out regulations relating to the following matters: (i) licences, permits and authorizations; (ii) security clearances; (iii) cannabis tracking system; (iv) cannabis products; (v) packaging and labelling; (vi) cannabis for medical purposes; and (vii) drugs containing cannabis.

#### *Licences, Permits and Authorizations*

The *Cannabis Regulations* establish six classes of licences under the *Cannabis Act* (Canada): (i) cultivation licences; (ii) processing licences; (iii) analytical testing licences; (iv) sales for medical purposes licences; (v) research licences; and (vi) cannabis drug licences. The *Cannabis Regulations* also create subclasses for cultivation licences (standard cultivation, micro-cultivation and nursery) and processing licences (standard processing and micro-processing). Different licences and each subclass therein, carry differing rules and requirements that are intended to be proportional to the public health and safety risks posed by each licence category and each subclass. The *Cannabis Regulations* provide that all licences issued under the *Cannabis Act* (Canada) will be valid for a period of no more than five years.

The *Cannabis Regulations* permit cultivation licence holders to conduct both outdoor and indoor cultivation of cannabis, however no licensed activities (except for destruction, antimicrobial treatment and distribution) can take place in a “dwelling-house”. The implications of the proposal to allow outdoor cultivation are not yet known, but such a development could be significant as it may reduce start-up capital required for new entrants in the cannabis industry. It may also ultimately lower prices as capital expenditure requirements related to growing outside are typically much lower than those associated with indoor growing.

#### *Security Clearances*

Certain people associated with cannabis licensees, including individuals occupying a “key position” such as directors, officers, large shareholders and individuals identified by the Canadian Minister of Health (the “Minister”), must hold a valid security clearance issued by the Minister. Under the *Cannabis Regulations*, the Minister may refuse to grant security clearances to individuals with associations to organized crime or with past convictions for, or an association with, drug trafficking, corruption or violent offences. This was largely the approach in place under the ACMPR and other related regulations governing the licensed production of cannabis for medical purposes. Individuals who have histories of non-violent, lower-risk criminal activity (for example, simple possession of cannabis, or small-scale cultivation of cannabis plants) are not precluded from participating in the legal cannabis industry, and the grant of security clearance to such individuals is at the discretion of the Minister and such applications will be reviewed on a case-by-case basis.

Security clearances issued under the ACMPR are considered to be security clearances for the purposes of the *Cannabis Act* (Canada) and the *Cannabis Regulations*. In addition, the *Cannabis Regulations* provide a three-month grace period for current

licence holders to identify those individuals that require security clearances and to apply for such security clearances (i.e. until January 17, 2019).

### ***Cannabis for Medical Purposes***

With the Cannabis Act (Canada) and the Cannabis Regulations coming into force on October 17, 2018, the medical cannabis regime migrated from the CDSA and the ACMPR to the Cannabis Act (Canada) and the Cannabis Regulations. The medical cannabis regulatory framework under the Cannabis Act (Canada) and the Cannabis Regulations remains substantively the same as existed under the CDSA and the ACMPR, with adjustments to create consistency with rules for non-medical use, improve patient access and reduce the risk of abuse within the medical access system.

Under Part 14 of the Cannabis Regulations, patients have three options for obtaining cannabis for medical purposes: (i) they can continue to access cannabis by registering with licensed producers; (ii) they can register with Health Canada to produce a limited amount of cannabis for their own medical purposes; or (iii) they can designate someone else to produce cannabis for them. With respect to (ii) and (iii), starting materials, such as marijuana plants or seeds, must be obtained from licensed producers. It is possible that (ii) and (iii) could significantly reduce the addressable market for the Company's products and could materially and adversely affect the business, financial condition and results of operations of the Company. However, management of the Company believes that many patients may be deterred from opting to proceed with options (ii) or (iii) since such steps require applying for and obtaining registration from Health Canada to grow cannabis, as well as the up-front costs of obtaining equipment and materials to produce such cannabis

### ***Cannabis Tracking System***

Under the Cannabis Act (Canada), the Minister is authorized to establish and maintain a national cannabis tracking system. The purpose of this system will be to track cannabis throughout the supply chain to help prevent diversion of cannabis into, and out of, the legal market. The Cannabis Regulations provide the Minister with the authority to make a ministerial order that would require certain persons named in such order to report specific information about their authorized activities with cannabis, in the form and manner specified by the Minister. The Minister has introduced the Cannabis Tracking and Licensing System, and licence holders are required to use this system to, among other things, submit monthly reports to the Minister.

### ***Health Products***

Health Canada has taken a scientific, evidenced-based approach for the oversight of health products with cannabis that are approved with health claims, including prescription and nonprescription drugs, natural health products, veterinary drugs and veterinary health products, and medical devices.

### **Regulatory Framework for Drugs**

#### ***Government Regulation and Product Approval***

Drugs are evaluated for safety, efficacy, and manufacturing quality as a condition of market access, and promotional messages must adhere to approved product labelling. Drug prices also are regulated in most countries with national health insurance systems. Regulation of market access and promotion derives from uncertainty about the real-life value of drugs. Real-life product characteristics can only be determined from accumulated experience over large numbers of patients in carefully designed epidemiological trials or observational studies.

As a biopharmaceutical company with pre-clinical and clinical stage programs that intends to test, register and commercialize products in Canada and the United States and other jurisdictions, the Company is subject to extensive regulation by various regulatory authorities. The primary regulatory agency in the United States is the FDA and in Canada it is Health Canada. Along with the foregoing, there are other federal, state, and local regulatory agencies. In the United States, the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and its implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products. Although the discussion below focuses on regulation in the United States, the Company anticipates seeking approval for, and marketing of, its products in other countries.

Generally, the Company's activities outside the United States will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Approval in the United States or Canada does

not assure approval by other regulatory agencies, although often test results from one country may be used in applications for regulatory approval in another country.

The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources and may not be successful. See “Risk Factors”.

The Company does not engage in any U.S. marijuana-related activities as defined in Canadian Securities Administrators Staff Notice 51-352 - Issuers with U.S. Marijuana-Related Activities. The Company has a research and/or business relationship with Sanyal Biotechnology LLC which is based in the U.S. and/or is a U.S. based company. Sanyal Biotechnology provides contract research services investigating the use of Cannabidiol in experimental models of autoimmune hepatitis. Revive intends to source CBD from a authorized licensed producer in Canada.

### ***New Drug Submissions (NDS) – Health Canada***

To obtain approval to market a drug in Canada, a sponsor usually requests a pre-submission meeting with the review division of Health Canada responsible for the therapeutic field. If the meeting is granted, the sponsor must submit a Pre-Submission Information package to the Therapeutic Products Directorate (“TPD”) to meet with the review division. This process occurs prior to submitting the New Drug Submission (“NDS”) application. The purpose of the pre-submission meeting is to review the evidence (non-clinical and clinical research, quality information, indication) that will be submitted in the NDS application.

During the drug development process, the sponsor prepares study reports. Once the sponsor releases the last study required for the submission, the sponsor completes the NDS application and submits it to TPD. Prior to submitting the NDS and if applicable based on the intended use of the product in the identified patient population, the sponsor may submit in advance a request for priority review status.

After submitting the NDS application, the file undergoes a screening process prior to being accepted for review. TPD has 45 calendar days from receipt to complete the screening review process. If granted a priority review, the screening period is reduced to 25 calendar days.

After a comprehensive review of an NDS application, Health Canada will issue a Notice of Compliance (“NOC”) if the product is approved or a Notice of Noncompliance if further questions remain. If a NOC is issued, a Drug Identification Number (DIN) is also issued that is required to be printed on each label of the product, as well as the final version of the Product Monograph that has been agreed to between Health Canada and the sponsor. The average target time for reaching a first decision on an NDS is 300 calendar days, unless the submission has received a priority review in which case the time is 180 calendar days.

Fees are levied for a review of an NDS application.

### **Regulatory Framework in the United States**

The FDA is the main regulatory body that controls pharmaceuticals in the United States, and its regulatory authority is based in the FDCA. Pharmaceutical products are also subject to other federal, state, and local statutes. A failure to comply explicitly with any requirements during the product development, approval, or post-approval periods, may lead to administrative or judicial sanctions. These sanctions could include the imposition by the FDA or an Investigational Review Board (“IRB”) of a hold on clinical trials, refusal to approve pending marketing applications or supplements, withdrawal of approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, or criminal prosecution. As presented on the section of the FDA’s website titled “Drug Review Process: Ensuring Drugs are Safe and Effective”<sup>1</sup>, the steps required before a new drug may be marketed in the United States generally include:

- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the Good Laboratory Practices (“GLP”) regulations;
- completion of extensive CMC (chemistry, manufacturing and control) to produce drug in accordance with current Good Manufacturing Practices (“cGMP”);

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<sup>1</sup> <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm>

- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent institutional review board (“IRB”) or ethics committee representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- preparation of and submission to the FDA of a new drug application (“NDA”) or biologics license application (“BLA”) after completion of all pivotal clinical trials;
- potential review of the product application by an FDA advisory committee, where appropriate and if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities where the proposed product is produced to assess compliance with cGMP;
- a potential FDA audit of the preclinical research and clinical trial sites that generated the data in support of the NDA or BLA; and
- FDA review and approval of an NDA or BLA prior to any commercial marketing or sale of the product in the United States

The preclinical research, including production of cGMP material, clinical testing and approval process require substantial time, effort, and financial resources, and Revive cannot be certain that any approvals for Revive’s product candidates will be granted on a timely basis, if at all.

### Clinical Trials

An IND is a request for authorization from the FDA to administer an investigational product candidate to humans. This authorization is required before interstate shipping and administration of any new drug product to humans in the United States that is not the subject of an approved FDA-NDA. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease under study, under the supervision of qualified investigators following GCPs, an international standard meant to protect the rights and health of patients with the disease under study and to define the roles of clinical trial sponsors, administrators, and monitors. Clinical trials are conducted under protocols that detail the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. Each protocol involving testing on patients in the United States and subsequent protocol amendments must be submitted to the FDA as part of the IND.

As set out in the July 1997 publication “ICH E8 Guideline – General Considerations for Clinical Trials”<sup>2</sup>, published by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, the three phases of clinical investigation are as follows:

- *Phase 1/Phase I.* Phase 1 includes the initial introduction of an investigational product candidate into humans. Phase 1 clinical trials may be conducted in patients with the target disease or condition, or in healthy volunteers. These studies are designed to evaluate the safety, metabolism, PK, and pharmacologic actions of the investigational product candidate in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational product’s PK and pharmacological effects may be obtained to inform the design of Phase 2 clinical trials. The total number of participants included in Phase 1 clinical trials varies, but is generally in the range of 20 to 80.
- *Phase 2/Phase II.* Phase 2 includes the controlled clinical trials conducted to evaluate the effectiveness of the investigational product for a particular indication(s) in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the

<sup>2</sup> [http://www.ich.org/fileadmin/Public\\_Web\\_Site/ICH\\_Products/Guidelines/Efficacy/E8/Step4/E8\\_Guideline.pdf](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E8/Step4/E8_Guideline.pdf)

product candidate. Phase 2 clinical trials are typically well-controlled, closely monitored, conducted in a limited subject population, and usually involve no more than several hundred participants

- Phase 3/Phase III. Phase 3 clinical trials are controlled clinical trials conducted in an expanded subject population at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the investigational product has been obtained, are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the product candidate, and to provide an adequate basis for drug approval. Phase 3 clinical trials usually involve several hundred to several thousand participants. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug.

The decision to terminate development of an investigational product may be made by either a health authority body, such as the FDA or IRB/ethics committees, or by a company for various reasons. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor or the clinical monitoring board. This group provides authorization for whether or not a trial may move forward at designated check points. These decisions are based on the limited access to data from the ongoing trial. The suspension or termination of development can occur during any phase of clinical trials if it is determined that the participants or patients are being exposed to an unacceptable health risk. In addition, there are requirements for the registration of ongoing clinical trials of products on public registries and the disclosure of certain information pertaining to the trials, as well as clinical trial results after completion.

#### New Drug Applications (NDA) – FDA

In order to obtain approval to market a drug in the United States, a marketing application must be submitted to the FDA that provides data establishing the safety and effectiveness of the product candidate for the proposed indication. The application includes all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results, as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational product candidate to the satisfaction of the FDA. In most cases, the NDA must be accompanied by a substantial user fee; there may be some instances in which the user fee is waived. The FDA will initially review the FDA-NDA for completeness before it accepts the FDA-NDA for filing. The FDA has 60 days from its receipt of an FDA-NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. After the FDA-NDA submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of FDA-NDAs. Most such applications for standard review products are reviewed within ten to twelve months. The FDA can extend this review by three months to consider certain late submitted information or information intended to clarify information already provided in the submission. The FDA reviews the FDA-NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP. The FDA may refer applications for novel products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an FDA-NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving an FDA-NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. After the FDA evaluates the FDA-NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the FDA-NDA, the FDA will issue an approval letter. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. Product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once

granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

### Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information (though not specifically required for Phase I trials) on a public website maintained by the U.S. National Institutes of Health, or NIH. Information related to the product, patient population, phase of investigation, study sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these trials after completion. Disclosure of the results of these trials can be delayed until the product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the design and progress of our development programs.

### Advertising and Promotion

As set out in the FDA's website discussion<sup>3</sup> on the "The Prescription Drug Marketing Act of 1987", the FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling (package insert) approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses – that is, uses not approved by the FDA and, therefore, not described in the drug's labeling – because the FDA does not regulate the practice of medicine. However, FDA regulations impose stringent restrictions on manufacturers' communications regarding off-label uses.

### Post-Approval Regulations

As set out in the FDA's website discussion<sup>4</sup> on "Post Marketing Requirements and Commitments", after regulatory approval of a drug is obtained, a company is required to comply with a number of post-approval requirements. For example, as a condition of approval of an FDA-NDA, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, as a holder of an approved FDA-NDA, a company would be required to report adverse reactions and production problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for any of its products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval to assure and preserve the long-term stability of the drug or biological product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural and substantive record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon a company and any third-party manufacturers that a company may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

### Controlled Substances

As described in Brian T. Yeh's 2012 publication<sup>5</sup> "The Controlled Substances Act: Regulatory Requirements", the United States federal Controlled Substances Act of 1970 (the "CSA"), and its implementing regulations establish a "closed system" of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation, and other requirements under the oversight of the U.S. Drug Enforcement Administration (the "DEA"). The DEA is the federal agency responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

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<sup>3</sup> <https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/significantamendmentstotheFDA/prescriptiondrugmarketingactof1987/default.htm>

<sup>4</sup> <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/post-marketingphaseivcommitments/default.htm>

<sup>5</sup> Yeh, BT. The Controlled Substances Act: Regulatory Requirements.

<https://www.amazon.com/Controlled-Substances-Act-Regulatory-Requirements-ebook/dp/B00BUBS8FC>

Facilities that research, manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies), and controlled substance schedule(s). For example, separate registrations are required for importation and manufacturing activities, and each registration authorizes which schedules of controlled substances the registrant may handle. However, certain coincident activities are permitted without obtaining a separate DEA registration, such as distribution of controlled substances by the manufacturer that produces them.

The DEA categorizes controlled substances into one of five schedules – Schedule I, II, III, IV, or V – with varying qualifications for listing in each schedule. Schedule I substances by definition have a high potential for abuse, have no currently “accepted medical use” in treatment in the United States, and lack accepted safety for use under medical supervision. They may be used only in federally-approved research programs and may not be marketed or sold for dispensing to patients in the United States. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV, or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence. The regulatory requirements are more restrictive for Schedule II substances than for Schedule III substances. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist in most situations, and cannot be refilled.

The DEA inspects all manufacturing facilities to review security, record keeping, reporting, and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes, and cages, and through use of alarm systems and surveillance cameras. Manufacturing facilities must maintain records documenting the manufacture, receipt, and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV, and V narcotic, and submit import or export declarations for Schedule III, IV, and V non-narcotics.

For drugs manufactured in the United States, the DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the United States based on the DEA’s estimate of the quantity needed to meet legitimate medical, scientific, research, and industrial needs.

The states also maintain separate controlled substance laws and regulations, including licensing, record keeping, security, distribution, and dispensing requirements. State Authorities, including Boards of Pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on our business, operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

### Marketing Exclusivity

As discussed in the May 19, 2015 issue<sup>6</sup> of the “FDA/CDER SBIA Chronicles” published by the FDA, upon FDA-NDA approval of a new chemical entity, which for this purpose is defined as a drug that contains no active moiety that has been approved by the FDA in any other FDA-NDA, that drug receives five years of marketing exclusivity during which the FDA cannot approve any abbreviated new drug application seeking approval of a generic version of that drug. Certain changes to the scope of an approval for a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approve an Abbreviated New Drug Application (“**ANDA**”) for a generic drug that includes the change. A Section 505(b)(2) FDA-NDA may be eligible for three-year marketing exclusivity, assuming the FDA-NDA includes reports of new clinical studies (other than bioequivalence studies) essential to the approval of the FDA-NDA.

An ANDA may be submitted one year before marketing exclusivity expires if a Paragraph IV certification is filed. In this case, the 30 months stay, if applicable, runs from the end of the five-year marketing exclusivity period. If there is no listed patent in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.

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<sup>6</sup> SBIA Chronicles. Patents and Exclusivity. May 19, 2015.  
<https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM447307.pdf>

Additionally, six months of marketing exclusivity in the United States is available under Section 505A of the FDCA if, in response to a written request from the FDA, a sponsor submits and the agency accepts requested information relating to the use of the approved drug in the pediatric population. This six-month pediatric exclusivity period is not a stand-alone exclusivity period, but rather is added to any existing patent or non-patent exclusivity period for which the drug product is eligible.

#### Patent Term Extension

As set out in the FDA's website discussion<sup>7</sup> "Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program", the term of a patent that covers an FDA approved drug may be eligible for patent-term extension, which provides patent-term restoration as compensation- for the patent term lost during the FDA regulatory review process. The United States Federal Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent-term extension of up to five years beyond the expiration of the patent. The length of the patent-term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Canada, Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug.

#### Compliance

During all phases of development (pre- and post-marketing), failure to comply with applicable regulatory requirements may result in administrative or judicial sanctions. These sanctions could include the FDA's imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, product detention, or refusal to permit the import or export of products, injunctions, fines, civil penalties, or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect.

#### ***Other Special Regulatory Procedures***

##### Fast Track Designation

According to the discussion<sup>8</sup> on the FDA's website on "Fast Track", under the Fast Track program, the sponsor of an IND may request the FDA to designate the drug candidate as a Fast Track drug if it is intended to treat a serious condition and fulfill an unmet medical need. The FDA must determine if the drug candidate qualifies for Fast Track designation within 60 days of receipt of the sponsor's request. Once the FDA designates a drug as a Fast Track candidate, it is required to facilitate the development and expedite the review of that drug by providing more frequent communication with and guidance to the sponsor.

In addition to other benefits such as the ability to use surrogate endpoints and have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track drug's FDA-NDA before the application is complete. This rolling review is available if the applicant provides, and the FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's review period for filing and reviewing an application does not begin until the last section of the FDA-NDA has been submitted. Additionally, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

##### Breakthrough Therapy Designation

According to discussion<sup>9</sup> on the FDA's website on "Breakthrough Therapy", the FDA may provide the Breakthrough Therapy designation to drugs to expedite the development and review of a candidate that is planned for use to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A Breakthrough Therapy designation includes all of the Fast Track program features, as well as more intensive FDA guidance on an efficient drug development program. The FDA also has an organizational commitment to involve senior management in such guidance.

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<sup>7</sup> <https://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm069959.htm>

<sup>8</sup> <https://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm>

<sup>9</sup> <https://www.fda.gov/ForPatients/Approvals/Fast/ucm405397.htm>



## Orphan Drug Designation

As set out in the FDA website discussion<sup>10</sup> on “Designating an Orphan Product: Drugs and Biological Products”, the FDA may grant Orphan Drug Designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or, if the disease or condition affects more than 200,000 individuals in the United States, if there is no reasonable expectation that the cost of developing and making the drug would be recovered from sales in the United States.

In the United States, Orphan Drug Designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax credits for certain research, and user fee waivers under certain circumstances. In addition, if a product receives the first FDA approval for the indication for which it has Orphan Drug Designation, the product is entitled to seven years of market exclusivity, which means the FDA may not approve any other application for the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

## Priority Review (United States)

Based on results of the Phase 3 clinical trial(s) submitted in an FDA-NDA, upon the request of an applicant, a priority review designation may be granted to a product by the FDA, which sets the target date for FDA action on the application at six months from the FDA’s decision on priority review application, or eight months from the FDA-NDA filing. According to the FDA website discussion<sup>11</sup> on “Priority Review”, this status is given where preliminary estimates indicate that a product, if approved, has the potential to provide a safe and effective therapy where no satisfactory alternative therapy exists, or a significant improvement compared to marketed products is possible. If criteria are not met for priority review, the standard FDA review period is ten months from the FDA’s decision on priority review application, or 12 months from the FDA-NDA filing. The priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

## Accelerated Approval

As set out in the FDA website discussion<sup>12</sup> on “Accelerated Approval”, under the FDA’s accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit. This approval mechanism is provided for under 21CFR314 Subpart H and Subpart E. In this case, clinical trials are conducted in which a surrogate endpoint is used as the primary outcome for approval. A surrogate endpoint is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. This surrogate endpoint substitutes for a direct measurement of how a patient feels, functions, or survives and is considered reasonably likely to predict clinical benefit. Such surrogate endpoints may be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. When the Phase 4 commitment is successfully completed, the biomarker is deemed to be a surrogate endpoint. Failure to conduct required post-approval studies or confirm a clinical benefit during post-marketing studies, could lead the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

## **DESCRIPTION OF THE BUSINESS OF REVIVE**

### **Overview**

The Company is a company focused on the research and development of therapeutics for medical needs and rare disorders. The Company’s novel delivery technology is being advanced to fill the medical needs for diseases and disorders such as pain and inflammation. Revive’s cannabinoid pharmaceutical portfolio partially focuses on rare liver diseases, and the FDA has

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<sup>10</sup> <https://www.fda.gov/forindustry/developingproductsforrareconditions/howtoapplyfororphanproductdesignation/default.htm>

<sup>11</sup> <https://www.fda.gov/forpatients/approvals/fast/default.htm>

<sup>12</sup> <https://www.fda.gov/ForPatients/Approvals/Fast/ucm405447.htm>

granted the Company orphan drug designations for CBD in the treatment of AIH and for CBD in the prevention of IRI resulting from solid organ transplantation. See “*List of Product Candidates*”, “*Research and Development Programs in Liver Diseases*” and “*Intangible Properties*”.

Together with its suppliers and contractors, the Company has expertise in pre-clinical and clinical research, regulatory, and business development activities. The Company’s goal is to use these core competencies to advance its product candidates along the regulatory and clinical pathway toward commercial approval. The Company believes it has the ability to manage and perform the key critical aspects of the drug or product development process, including conducting or managing pre-clinical studies, clinical trials, developing and executing strategies for the protection of intellectual property, and interacting with regulatory authorities. The Company is actively seeking development and commercial partnerships that might facilitate these activities. In the meantime, it plans to advance its drug and product candidates and technologies toward commercial approval in the most efficient and expeditious manner.

The Company is also actively engaging in a review of certain complimentary assets that it may consider acquiring or licensing. For example it licensed a potential novel delivery technology asset from WARF. The Company also entered into the SCRF License Agreement with SCRF, pursuant to which it was granted an exclusive license to develop and commercialize a portfolio of patents based on cannabinoid-based therapeutics, such as CBD, in the treatment of AIH. See “*Research and Development Programs in Liver Diseases*” and “*Intangible Properties*”.

### **Strategy**

Upon licensing a product candidate, the Company’s strategy is to apply its expertise and its partners’ expertise to advance the product toward regulatory approval and commercial sale in major markets, including the U.S. and Canada. These activities include implementing intellectual property protection and registration strategies, formulating or reformulating existing drug products, performing or managing clinical trials in target jurisdictions, undertaking or managing the collection, collation and interpretation of research and clinical data, and submitting such data to the relevant regulatory authorities in compliance with applicable protocols and standards.

The Company may also develop next-generation versions of its product candidates, which will aim to improve upon the product candidate, and may have the potential to treat existing diseases better or new diseases that would otherwise remain untreated by the original product. The Company may also develop and commercialize cannabinoid-based products for the medical and recreational marijuana markets.

In order to augment its ability to develop product candidates and effectively market any products in respect of which it obtains regulatory approval, the Company may seek to enter into an agreement or partnership with licensed producers of medical marijuana and biopharmaceutical companies that have development and/or sales and marketing capabilities. Entering into an agreement or partnership with an organization that has these capabilities may enable the Company to increase profitability and further accelerate development of its product candidates or enable it to develop the candidate in more than one indication, simultaneously.

In order to optimize the development of its product candidates, the Company outsources certain aspects of its research and product development activities. Factors that the Company considers in determining which activities to outsource include cost, relative expertise, capacity, and quality assurance. Product development functions that the Company has chosen to historically outsource include pre-clinical activities in support of regulatory filings, clinical trials, and manufacturing. The Company believes that its relationships with external laboratories enable it to complete pre-clinical testing faster and more efficiently than it can perform these activities in-house. Additionally, the Company will engage with independent contract research organizations that are specifically equipped to manage future clinical trial and research projects, thus alleviating the need for it to commit redundant internal resources. For now, the Company believes that it is more efficient to outsource product manufacturing to contract manufacturing organizations and third-party suppliers.

The Company is in discussions with Canadian late-stage and licensed producers of cannabis to evaluate strategic collaborations for the Company’s products, cannabinoid delivery system, liver research program, and intellectual property in developing and commercializing products for the cannabis and health and wellness market. The Company has secured and is also evaluating exclusive rights to unique cannabis-based products and technologies for the Canadian market. See “*Proposed buccal cannabinoid delivery technology*” and “*Intangible Properties*”.

## Products under Development

### *Bucillamine*

Bucillamine (N-(mercapto-2-methylpropionyl)-l-cysteine), which has a well-known safety profile and is prescribed in the treatment of rheumatoid arthritis in Japan and South Korea for over 30 years, is a cysteine derivative with 2 thiol groups that is 16-fold more potent than N-acetylcysteine (“NAC”) as a thiol donor in vivo, giving it vastly superior function in restoring glutathione and therefore greater potential to prevent acute lung injury during influenza infection. (Horowitz LD. Bucillamine: a potent thiol donor with multiple clinical applications. *Cardiovasc Drug Rev.* 2003 Summer;21(2):77-90.) Bucillamine has also been shown to prevent oxidative and reperfusion injury in heart and liver tissues\* and is highly cell permeable for efficient delivery into cells. Horowitz LD. Bucillamine: a potent thiol donor with multiple clinical applications. *Cardiovasc Drug Rev.* 2003 Summer;21(2):77-90.; Sagawa A, Fujisaku A, Ohnishi K et al. A multicentre trial of bucillamine in the treatment of early rheumatoid arthritis (SNOW study). *Mod Rheumatol.* 2011 Jun;21(3):251-7. doi: 10.1007/s10165-010-0385-4.)

Preclinical and clinical studies have demonstrated that reactive oxygen species contribute to the destruction and programmed cell death of pulmonary epithelial cells.<sup>1</sup> N-acetyl-cysteine (NAC) has been shown to significantly attenuate clinical symptoms in respiratory viral infections in animals and humans, primarily via donation of thiols to increase antioxidant activity of cellular glutathione.<sup>4-7</sup> In addition, it was found that thiol-based drugs decrease binding of SARS-CoV-2 spike protein to its receptor, decrease the entry efficiency of SARS-CoV-2 spike pseudotyped virus, and inhibit SARS-CoV-2 live virus infection.<sup>6</sup>

The Company initiated activities to explore the use of Bucillamine as a potential treatment for infectious diseases including influenza and the coronavirus disease (“COVID-19”). The Company filed its pre-IND meeting with the FDA and it received feedback from the FDA that recommended that the Company proceed directly into a Phase 3 confirmatory clinical trial (“Phase 3 study”) to evaluate Bucillamine for the treatment of patients with mild-moderate COVID-19 due to the SARS-CoV-2 infection in order to ensure expeditious evaluation of the safety and efficacy of Bucillamine. The Company announced on June 20, 2020 the submitted today its Investigational New Drug application to the FDA for a Phase 3 confirmatory study for Bucillamine as a potential treatment in COVID-19.

### *Drug delivery technology*

The drug delivery technology aims to deliver both synthetic and natural extracts of psychedelics, such as psilocybin, and cannabinoids, such as cannabidiol in a potential number of ways including topical gels, creams or ointments, oral or transdermal patches, oral dosages and foams. The Company’s Tannin-Chitosan composite drug delivery technology, in which the Company has an exclusive license with the Wisconsin Alumni Research Foundation, is a natural, non-toxic, biodegradable and biocompatible composite that combines a tannin material, which is derived from a plant group having antibacterial, antifungal, antioxidant and wound healing properties, and a chitosan material, which is derived from the crustacean group having blood-clotting and antimicrobial properties. The delivery technology has a rapid onset of action and controlled or sustained release potential capabilities and may allow combining multiple extracts from mushrooms or cannabinoids in one formulation. The Company is investigating novel oral dosage forms of psilocybin, such as oral dissolvable thin films.

### *Psilocybin*

Psilocybin is a naturally occurring psychedelic prodrug compound produced by more than 200 species of mushrooms, collectively known as psilocybin mushrooms. The most potent are members of the genus *Psilocybe*, such as *P.azurescens*, *P.semilanceata*, and *P.cyanescens*, but psilocybin has also been isolated from about a dozen other genera. As a prodrug, psilocybin is quickly converted by the body to psilocin, which has mind-altering effects similar, in some aspects, to those of LSD, mescaline, and DMT. In general, the effects include euphoria, visual and mental hallucinations, changes in perception, a distorted sense of time, and spiritual experiences, and can also include possible adverse reactions such as nausea and panic attacks.

The intensity and duration of the effects of psilocybin are variable, depending on species or cultivar of mushrooms, dosage, individual physiology, and set and setting. Once ingested, psilocybin is rapidly metabolized to psilocin, which then acts on serotonin receptors in the brain. The mind-altering effects of psilocybin typically last from two to six hours, although to individuals under the influence of psilocybin, the effects may seem to last much longer, since the drug can distort the perception of time. Psilocybin has a low toxicity and a low harm potential.

## Medical Uses and Clinical Studies for Psilocybin

Although psilocybin has been used for centuries in rituals, modern medicine has recently reported clinical studies, as well. A report was published in the *Journal of Psychopharmacology*<sup>13</sup> detailing two small studies that noted the ingredient in “magic mushrooms” - psilocybin - can reverse the feeling of “existential distress” that patients often feel after being treated for cancer. Reportedly, cancer can leave patients with this type of psychiatric disorder, feeling that life has no meaning. Typical treatments such as antidepressants may not be effective. However, use of a single dose of synthetic psilocybin reversed the distress felt by the patients and was a long-term effect. Some advanced cancer patients described the effect from the drug as if “the cloud of doom seemed to lift.”

A second study from the U.K. in the *Journal of Psychopharmacology*<sup>14</sup> suggested that when given to patients with treatment-resistant depression, psilocybin affected “functional connectivity” changes in the brain which was evident in scans. The study suggested that “psilocybin therapy improves how the brain works and revives emotional responsiveness.”

Two additional studies using psilocybin were completed: one at New York University (“NYU”) Langone Medical Center in New York City and one at Johns Hopkins Medical School in Baltimore. For both studies, trained monitors were with patients as they experienced the effects of the drug, which can lead to hallucinations.

- In the NYU study<sup>15</sup>, 29 patients with advanced cancer were given either a single dose of psilocybin or the B vitamin known as niacin, both in conjunction with psychotherapy. After seven weeks, the patients switched treatments (a cross-over study). In 60% to 80% of the patients receiving psilocybin, a relief from distress occurred rapidly and lasted over six months. The long-term effect was evaluated by researchers looking at test scores for depression and anxiety.
- In the Johns Hopkins<sup>16</sup> study, researchers treated 51 adults with advanced cancer with a small dose of psilocybin followed five weeks later with a higher dose, with a 6-month follow-up. As with the NYU study, about 80% of participants experienced clinically significant relief from their anxiety and depression that lasted up to six months.

At the Center for Psychedelic and Consciousness Research at Johns Hopkins University in Baltimore, Maryland, researchers are focusing on how psychedelics affect behavior, mood, cognition, brain function, and biological markers of health. This research group was the first to obtain U.S. regulatory approval to continue research with psychedelics in healthy volunteers.

Additional studies with psilocybin are expected, and one is comparing the chemical against a leading traditional antidepressant. As reported by Johns Hopkins, upcoming studies will evaluate the use of psilocybin as a new therapy for opioid addiction, Alzheimer's disease, post-traumatic stress disorder (PTSD), post-treatment Lyme disease syndrome (formerly known as chronic Lyme disease), anorexia nervosa and alcohol use in people with major depression. A focus on precision medicine tailored to the individual patient is expected.

## Legal Status of Psilocybin

The legal status of unauthorised actions with psilocybin mushrooms varies worldwide. Psilocybin and psilocin are listed as Schedule I drugs under the United Nations 1971 Convention on Psychotropic Substances. Schedule I drugs are defined as drugs with a high potential for abuse or drugs that have no recognized medical uses. However, psilocybin mushrooms have had numerous medicinal uses in dozens of cultures and have a significantly lower potential for abuse than other Schedule I drugs.

Psilocybin mushrooms are not regulated by UN treaties. From a letter, dated 13 September 2001, from Herbert Schaepe, Secretary of the UN International Narcotics Control Board, to the Dutch Ministry of Health:

“As you are aware, mushrooms containing the above substances are collected and used for their hallucinogenic effects. As a matter of international law, no plants (natural material) containing psilocine and psilocybin are at present controlled under the Convention on Psychotropic Substances of 1971. Consequently, preparations made of these plants are not under international control and, therefore, not subject of the articles of the 1971 Convention. Criminal cases are decided with reference to domestic law, which may otherwise provide for controls over mushrooms containing psilocine and psilocybin. As the Board can only speak as to the contours of the international drug conventions, I am unable to provide an opinion on the litigation in question.”

<sup>13</sup> <https://journals.sagepub.com/doi/10.1177/0269881119897615>

<sup>14</sup> <https://journals.sagepub.com/doi/10.1177/0269881119895520>

<sup>15</sup> <https://pubmed.ncbi.nlm.nih.gov/27909164/>

<sup>16</sup> <https://journals.sagepub.com/doi/full/10.1177/0269881116675513>

Many countries, however, have some level of regulation or prohibition of psilocybin mushrooms (for example, the US Psychotropic Substances Act, the UK Misuse of Drugs Act 1971, and the Canadian Controlled Drugs and Substances Act). The prohibition of psilocybin mushrooms has come under criticism, from the general public and from researchers who see therapeutic potential with regard to drug addictions and other mental instabilities, such as PTSD, anxiety and depression, as well as cluster headaches. Among regulated drugs, psilocybin mushrooms also have relatively few medical risks.

In many national, state, and provincial drug laws, there is a great deal of ambiguity about the legal status of psilocybin mushrooms, as well as a strong element of selective enforcement in some places, since psilocybin and psilocin are deemed illegal to possess without license as substances, but mushrooms themselves are not mentioned in these laws. The legal status of Psilocybe spores is even more ambiguous, as the spores contain neither psilocybin nor psilocin, and hence are not illegal to sell or possess in many jurisdictions, though many jurisdictions will prosecute under broader laws prohibiting items that are used in drug manufacture. A few jurisdictions (such as the US states of California, Georgia and Idaho) have specifically prohibited the sale and possession of psilocybin mushroom spores. Cultivation of psilocybin mushrooms is considered drug manufacture in most jurisdictions and is often severely penalized, though some countries and one US state (Florida) has ruled that growing psilocybin mushrooms does not qualify as “manufacturing” a controlled substance.<sup>17</sup>

Under Canadian law, mushroom spore kits are legal and are sold openly in stores or on the internet as the spores and kits themselves are legal. Psilocybin and psilocin are illegal to possess, obtain or produce without a prescription or license as they are schedule III under the Controlled Drugs and Substances Act. Online dispensaries exist that openly sell microdoses to Canadian patients with medical prescriptions. The police tolerates the activity, citing focus on more harmful criminal drug activities. In September 2019, a motion to prevent the sale of magic mushrooms was defeated by Vancouver council. Efforts are underway to obtain exemptions for medical and research use under CDSA Section 56.

In November 2019, the FDA designated psilocybin therapy as a “breakthrough therapy” for depression to the Usona Institute, an action the agency uses to speed up development and review of investigational drugs. Breakthrough therapies are expected to provide a major improvement over currently available agents for an unmet medical need.

Usona’s PSIL201 psilocybin U.S. clinical trial is a Phase 2 study evaluating psilocybin as a treatment for Major Depressive Disorder (“MDD”). This research will use a randomized, double-blind, placebo-controlled study design to measure the antidepressant effects of a single dose of psilocybin in 80 patients between 21 to 65 years of age with MDD. According to the manufacturer, “psilocybin potentially offers a novel paradigm in which a short-acting compound imparts profound alterations in consciousness and could enable long-term remission of depressive symptoms.”

The Company, under a sponsored research partnership agreement with the University of Wisconsin-Madison, is evaluating novel formulations and drug delivery technology focused on psilocybin-based pharmaceuticals. The research program is being conducted at the Reed Research Group and will be led by Dr. Jess D. Reed, Ph.D., Professor of Animal Sciences at the University of Wisconsin-Madison. Under the agreement, Dr. Reed and his research team will evaluate psilocybin-based formulations and the patented Tannin-Chitosan composite drug delivery technology for psilocybin, in which the Company has an exclusive license with the Wisconsin Alumni Research Foundation.

Through initial evaluations with the Company’s research team, it has been found there are several unique parallels between the Company’s intellectual property portfolio of psilocybin-based formulations and delivery mechanism and the drug delivery technology, which is comprised of tannin-chitosan composites that have been studied with cannabidiol in the past. Revive intends to research both delivery mechanisms in parallel as each provides its own unique qualities such as the potential of rapid onset of action and time-release compositions. The future of psilocybin as a medication will come in many forms. The Company believes that the most optimal delivery method to pursue and unlock the potential of psilocybin to treat a broad spectrum of diseases and disorders will be in the form of both an oral dissolvable tablet and an oral thin film strip, commonly recognized as a ‘Breath Strip’. The Company is preparing its formulation development plans intending to pursue clinical studies for indications currently not being evaluated with psilocybin. It is believed that the combination of psilocybin and our tannin-chitosan delivery platform gives us a unique advantage.

Revive’s psilocybin-based formulations have been engineered to work synergistically with the body’s own natural pathways of absorption while offering a contemporary approach to consumption. The research and development work being carried out at the University of Wisconsin-Madison focuses on tannin-chitosan composites in the form of thin films, hydrogels and 3D

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<sup>17</sup> <https://www.abqjournal.com/news/state/apmush06-15-05.htm>

foams. The research will include the development of composite formulations, physio-chemical characterization (e.g. tensile strength of films) of composite materials and rate of psilocybin release from composites. Final formulations will be investigated in pre-clinical and clinical studies in various diseases and disorders. The Company has identified tannin-chitosan composite thin films as the lead candidate for the development of a unique delivery platform for therapeutic doses (1-20mg) of psilocybin into the oral cavity.

### ***Cannabinoids***

There are over 100 known cannabinoid compounds derived from the cannabis plant. The two primary cannabinoids used widely for medical and/or pharmaceutical purposes are Tetrahydrocannabinol (“**THC**”) and CBD. It is widely known that THC is a major psychoactive cannabinoid and is a partial agonist of the cannabinoid receptor type 1 (CB1) and cannabinoid receptor type 2 (CB2) receptors and is widely used in pain management. CBD acts on many of the same receptors as THC, but without the psychoactive side effects. Clinical and pre-clinical data suggest that THC has positive effects on treating pain and CBD has positive effects on treating pain as well as, but is not limited to, a number of inflammatory diseases, skin disorders, and liver diseases.

The Company is focused on commercializing differentiated branded cannabis-based products, including products that have patent protection and best-in-class with first mover advantage offering a better alternative over conventional cannabis-based products in the market. The Company has assembled rights to a patent portfolio related to cannabinoid delivery systems and cannabinoid uses for liver diseases. See “*Intangible Properties*”.

The Company explored the potential of its drug delivery technology to deliver CBD in combination with chitosan and tannins in a controlled or sustained release fashion, systemically or locally, through the skin. The Company’s drug delivery technology was founded by Dr. Jess D. Reed, Ph.D., Professor of Animal Sciences at the University of Wisconsin-Madison. See “*Exclusive Worldwide Licence Agreement with WARF*”.

The Company explored the use of a buccal delivery technology involving chewing gum from Axim. The Company, through Revive Therapeutics Inc., and Axim entered into the Axim Agreement in connection with the exclusive commercialization of Axim’s CanChew™ product, a CBD-based controlled release chewing gum, in Canada. Pursuant to the Axim Agreement, Axim has appointed the Company as its exclusive distributor of the CanChew™ product in Canada and it also includes a grant to Revive from Axim of an exclusive, fully paid-up, royalty-free sublicensable right and license to use the certain patents and know-how in connection with the marketing, distribution and sale of the CanChew™ product in Canada. The Company is no longer pursuing regulatory approval in Canada. The terms of the Axim Agreement, the Company has annual minimum purchase amount obligations, which increase each year for the term of the agreement. The Axim Agreement expired on December 31, 2020 and has not been renewed.

The Company is additionally engaged in evaluating the use of cannabidiol (“**CBD**”) in the treatment of autoimmune hepatitis (“**AIH**”) and in the prevention of ischemia/reperfusion injury resulting from solid organ transplantation. The Company, through Revive Therapeutics Inc., entered into a research collaboration with SanyalBio focused on advancing cannabinoids for the potential treatment of liver diseases. The research conducted is to develop a novel AIH model based on SanyalBio’s DIAMOND™ model. This research collaboration is expected to generate a better model of AIH which will enable SanyalBio to further advance the research of cannabinoids for the treatment of AIH and other liver diseases, and the research will provide meaningful information to support future clinical research and partnering discussions for Revive.

### **Exclusive Worldwide License Agreement with SCRF**

Pursuant to the SCRF License Agreement, the Company, through Revive Therapeutics Inc., was granted an exclusive license from SCRF to develop and commercialize a portfolio of patents based on cannabinoid-based therapeutics, such as CBD, in the treatment of AIH. Under the agreement, the Company agreed to pay SCRF a one time fee for entering into the license, as well as certain milestone payments to SCRF. The Company also agreed to pay SCRF escalating annual minimum royalty payments commencing in 2020. SCRF License Agreement is subject to the US Government’s right to use the intellectual property for its own purposes and reserve the right to allow others to use the inventions for non-profit purposes.

### **Exclusive Worldwide License Agreement with WARF**

Based on the results of the University of Wisconsin-Madison Research Program, the Company, through Revive Inc., entered into the WARF License Agreement. Pursuant to the WARF License Agreement, the Company gained exclusive, royalty-bearing, worldwide rights to intellectual property for the development and commercialization of cannabinoid-based products

for therapeutic and/or prophylactic purposes delivered via topical, subcutaneous, buccal-mucosal or oral applications; including seeking out the necessary regulatory approvals necessary for the development and commercialization of such products. Under the terms of the WARF License Agreement, the Company agreed to pay WARF a one-time fee, certain milestone payments, as well as escalating annual minimum royalty payments commencing in 2027. The WARF License Agreement is subject to the US Government's right to use the intellectual property for its own purposes and reserve the right to allow others to use the inventions for non-profit purposes.

### List of Product Candidates

The following chart sets out the Company's product candidates that are described in this AIF, including the program name, status, expected milestones, the amount spent on the product candidate during the financial year ended June 30, 2020, the estimated cost to complete the product candidate and the Company's commercialization rights with respect to the product candidate.

Program	Status	Next Milestone	Amount Spent during Financial Year ended June 30, 2020	Estimated Cost to Complete (2021)	Commercialization Rights
Psilocybin based formulations	Sponsored research agreement with the University of Wisconsin-Madison	Initiate research and development of formulations	\$42,827 was spent during the year ended June 30, 2020	\$500,000	Worldwide
Delivery Technology	Signed WARF License Agreement for cannabinoids and hallucinogenic compounds. Completed the University of Wisconsin-Madison Research Program for cannabinoids	Conduct research and development of formulations Conduct research studies in various disease models	\$70,695 was spent during the year ended June 30, 2020	\$150,000	Worldwide
Cannabinoids for Liver Diseases	Signed SCRF License Agreement. Completed research study in establishing AIH in SanyalBio's mice model.	Initiate human clinical study in AIH	No funds were spent during the year ended June 30, 2020	\$200,000	Worldwide
Cannabinoid Products	Signed Axim Agreement with Axim for CBDbased chewing gum.	Currently Health Canada regulations do not allow import of CBD into Canada	\$6,653 was spent during the year ended June 30, 2020	-	Canada

### Competitive Conditions

The Company's competitors include multinational pharmaceutical companies and specialized biotechnology companies, medical cannabis licensees, universities, and other research institutions that are conducting research in cannabinoid products.

The Company plans to compete in a growing cannabis industry with an increasing number of participants subject to rapid changes and developments. The Company will face the challenge of competing with companies of varying sizes and at varying stages of licensing and levels of development of related products in the cannabis industry. Other companies working in cannabinoid research may develop products targeting the same conditions that the Company may be focusing on, and such competing products may be superior to the Company's potential products.

More established companies may have a competitive advantage over the Company due to their greater size, capital resources, cash flows, and institutional experience. Compared to the Company, many of competitors may have significantly greater financial, technical, and human resources at their disposal. Due to these factors, competitors may have an advantage in marketing their approved products and may obtain regulatory approval of their product candidates before the Company can,

which may limit the Company's ability to develop or commercialize its product candidates. Competitors may also develop drugs that are safer, more effective, more widely used, and less expensive, and may also be more successful in manufacturing and marketing their products. These advantages could materially impact the Company's ability to develop and commercialize its products.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of the Company's competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties also compete with the Company in recruiting and retaining qualified personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the Company's programs. See "*Risk Factors*".

### **Specialized Skill and Knowledge**

Numerous aspects of the Company's business require specialized skills and knowledge, including those relating to business operations, regulatory compliance and finance. Furthermore, the research and development of alternative uses for pharmaceutical compounds such as cannabinoids requires specialized scientific and medical skill and knowledge. Revive has been successful to date in identifying and retaining employees and contractors with the aforementioned skills and knowledge. See "*Risk Factors*".

### **Intangible Properties**

The Company has assembled rights to a patent portfolio related to cannabinoid delivery systems and cannabinoid uses for specific diseases pursuant to agreements entered into by Revive Inc. with each of WARF, SCRF and Axim. This patent portfolio includes six issued U.S. patents and one issued Canadian patent.

The Company has also been assigned exclusive rights in certain patents in the United States related to the use of the drug Bucillamine in the treatment of gout.

The Company expects its intellectual property portfolio to be significant to its business going forward. See "*Risk Factors*".

### **Employees**

As of the date of this AIF, Revive does not have any employees. Revive depends on certain key members of its management and scientific staff and the loss of services of one or more of these persons could adversely affect the Company.

Revive also uses consultants and outside contractors to carry on many of the Company's activities, including preclinical testing and validation, formulation, assay development, manufacturing, clinical and regulatory affairs and clinical trials.

### **Reorganizations**

Since July 1, 2019, the Company and its subsidiary have not been the subject of a material reorganization.

## **DESCRIPTION OF CAPITAL STRUCTURE**

The authorized share capital of the Company consists of an unlimited number of common shares. As at the date of this AIF, there are 260,897,889 common shares issued and outstanding. All common shares are fully paid and have no par value.

Each common share entitles the holder thereof to receive notice of any meetings of the shareholders of Revive, to attend and to cast one vote per common share at all such meetings. Holders of common shares do not have cumulative voting rights with respect to the election of directors and, accordingly, holders of a majority of the common shares entitled to vote in any election of directors may elect all of the directors standing for election. Holders of common shares are entitled to receive on a pro rata basis such dividends, if any, as and when declared by the Board at its discretion from funds legally available therefore and, upon the liquidation, dissolution or winding up of Revive, are entitled to receive on a pro rata basis the net assets of the Company for payment of debts and liabilities. The common shares do not carry any pre-emptive, subscription, redemption, retraction or conversion rights, nor do they contain any sinking or purchase fund provisions.



## DIVIDENDS AND DISTRIBUTIONS

Revive has not declared or paid any dividends or distributions on its common shares to date. The payments of dividends or distributions in the future are dependent on Revive’s earnings, financial condition and such other factors as its Board of Directors considers appropriate. Revive currently does not anticipate paying any dividends in the foreseeable future due to its stage of development.

## MARKET FOR SECURITIES

### *Trading Price and Volume*

The common shares commenced trading through the facilities of the Canadian Securities Exchange (“CSE”) on July 19, 2019 under the trading symbol “RVV”. Prior thereto, the common shares were listed for trading on the TSX Venture Exchange under the symbol “RVV”.

The following table sets forth, for the periods indicated, the reported high and low trading prices and the aggregate volume of trading of the common shares on the TSX Venture Exchange for the fiscal year ended June 30, 2020.

Month	High (\$)	Low (\$)	Volume
July 2019	0.09	0.075	188,600
August 2019	0.075	0.05	1,968,940
September 2019	0.07	0.05	1,526,890
October 2019	0.06	0.04	1,165,320
November 2019	0.045	0.025	3,043,130
December 2019	0.06	0.025	5,642,360
January 2020	0.06	0.035	8,439,340
February 2020	0.075	0.045	11,060,680
March 2020	0.105	0.045	36,417,190
April 2020	0.185	0.105	34,978,700
May 2020	0.36	0.13	40,602,810
June 2020	0.33	0.175	38,587,060

### *Prior Sales*

In the twelve month period preceding June 30, 2020, the following common shares in the capital of the Company have been issued:

<u>Date</u>	<u>Number of Common Shares</u>	<u>Issue Price Per Issuer Common Share</u>	<u>Aggregate Issue Price</u>	<u>Consideration Received</u>
February 10, 2020	3,000,000 <sup>(1)</sup>	\$0.055	\$165,000	Acquisition
March 5, 2020	55,000,000 <sup>(2)</sup>	\$0.05	\$2,750,000	Acquisition
March 18, 2020	33,535,000 <sup>(3)</sup>	\$0.05	\$1,676,750	Cash
April 9, 2020	9,062,495 <sup>(4)</sup>	\$0.05	\$453,550	Cancellation of Debt
April 14, 2020	16,400,000 <sup>(5)</sup>	\$0.05	\$820,000	Cash
June 11, 2020	4,368,000 <sup>(6)</sup>	\$0.05	\$218,400	Conversion of Debenture

Notes:

- (1) These shares were issued in connection with the acquisition of shares in the capital of Red Light Holland Financing Inc. pursuant to a supply and collaboration agreement with Red Light Holland Financing Inc.

- (2) These shares were issued in connection with the acquisition of all of the issued and outstanding shares in the capital of Psilocin Pharma Corp.
- (3) These shares were issued pursuant to the private placement.
- (4) These shares were issued pursuant to various debt conversion agreements.
- (5) These shares were issued pursuant to the private placement.
- (6) These shares were issued pursuant to the conversion of the principal amount and accrued interest of a debenture.
- (7) An aggregate of 5,220,734 shares were issued pursuant to the exercise of warrants.
- (8) An aggregate of 42,000 shares were issued pursuant to the exercise of broker warrants.
- (9) An aggregate of 850,000 shares were issued pursuant to the exercise of stock options.

## DIRECTORS AND OFFICERS

### *Directors*

The following table lists the names, municipalities of residence and principal occupations of the directors and officers of the Company. Each director will hold office until the next annual meeting of shareholders or until a successor is elected or appointed.

<b>Name and Province or State and Country of Residence</b>	<b>Director Since</b>	<b>Office Held and Principal Occupation</b>
Michael Frank Thornhill, Ontario	December 2019	Director, Chairman and Chief Executive Officer of Revive and President of Mifram Consulting
William Jackson Hamilton, Ontario	January 2014	Director and Chief Executive Officer of Atwill Medical Solutions Inc.
Joshua Herman Toronto, Ontario	December 2019	Director and Chief Executive Officer of Herman Holdings Limited
Christian Scovenna Etobicoke, Ontario	December 2019	Director and Director & Sr. VP of Corporate Development for Pasofino Gold Limited
Andrew Lindzon Toronto, Ontario	December 2019	Director and Chief Executive Officer of Ashlin Technology Solutions

### *Committees of the Board*

The members of the Audit Committee as of June 30, 2020 were Andrew Lindzon (Chair), William Jackson and Michael Frank.

### *Biographies of Directors*

Michael Frank - Mr. Frank has a strong background in operations, business development, M&A and the capital markets. Mr. Frank is currently the President of Mifram Consulting, providing advisory services to emerging technology companies in a number of key verticals. In the past, Mr. Frank has served as the CEO and Director of Sprylogics International and the Internet of Things Inc., as well as holding senior management positions at Ernst & Young, Data General, and NCR. Mr. Frank has had successful exits in the technology sector including one to Intuit Corporation, and has been instrumental in advising several early stage software companies including a number in the cannabis sector over the last few years. Additionally, Mr. Frank has consulted to Revive's senior management team on various strategic initiatives.

William Jackson - Mr. Jackson is currently Chief Executive Officer of Atwill Medical Solutions. Mr. Jackson was a cofounder of Covalon Technologies Ltd. (TSXV: COV) and held senior management roles such as Chief Financial Officer, Chief Operating Officer and Chief Business Officer, and director from December 2004 to January 2013. Mr. Jackson served as a director of Titan Medical Inc. (TSXV: TMD) from April 2008 to June 2010.

Joshua Herman – Mr. Herman was a corporate accountant at Hennick Herman for 8 years where he focused on advising clients on various transactional, accounting and tax issues. In 2015, Mr. Herman began early-stage investing in the medical marijuana industry, where he has since become a prolific and well known investor. In 2017, Mr. Herman founded Herman Holdings in order to capitalize on the top investment opportunities he has access to within the cannabis space

Christian Scovenna - Mr. Scovenna a highly-experienced C-Suite Executive with over twelve years of capital market experience. In his most recent engagement with Mojave Jane Brands Inc. (formerly, High Hampton Holdings Corp.) (CSE: JANE), he was instrumental in building the company as one of the original founders and was a key member of the management team as interim CEO and Senior VP Corporate Finance while also serving on the board as a director. As Managing Director at a boutique firm, Mr. Scovenna led six portfolio companies within the group where he focused on raising capital and business development. He also spent four years with Frontier Merchant Capital Group as Director & Senior VP of Operations and served as Managing Partner with Lions Edge Capital. Over the years, Mr. Scovenna has been successful in completing numerous M&A activities and capital raises. He currently serves as Director & Sr. VP of Corporate Development for Pasofino Gold Limited (formerly Enforcer Gold Corp.) (VEIN-TSX.V) and Tevano Payment Systems (Private Co.) as VP Of Corporate Development

Andrew Lindzon - Mr. Lindzon is a seasoned professional and investor with an excellent track record. He earned an LLB from Osgoode Hall (1984) and is CEO of Ashlin Technology Solutions since 1985. Ashlin provides North American companies with technology products and services to improve business processes

#### *Executive Officers*

The names, municipalities of residence and titles of the Executive Officers of Revive as of December 31, 2017 were:

<b>Name and Municipality of Residence</b>	<b>Office</b>
Michael Frank <sup>(1)</sup> Thornhill, Ontario	Chairman and Chief Executive Officer
Carmelo Marrelli Woodbridge, Ontario	Chief Financial Officer

Notes:

(1) For Mr. Frank’s biography, please see “Biographies of Directors” under “Directors and Officers” in this AIF.

#### *Biographies of Executive Officers*

Carmelo Marrelli – Mr. Marrelli holds a Bachelor of Commerce degree from the University of Toronto and is qualified as a Chartered Accountant and as a Certified General Accountant in Canada. Mr. Marrelli has been a principal of Marrelli Support Services Inc., a firm providing administration services to Canadian public companies, since February 2009 and, prior to February 2009, a partner with Marrelli & Drake Corporate Services (formerly Duguay & Ringler Corporate Services) (a firm providing administration services to Canadian public companies). Mr. Marrelli also serves as the Chief Financial Officer of several publicly-listed junior mining companies and as a director of Odyssey Resources Limited, an Exchange listed issuer.

#### *Security Holdings of Directors and Executive Officers*

To the knowledge of the Company, the directors and executive officers of the Company listed in this AIF beneficially own, directly or indirectly, or exercise control or direction over as of June 30, 2020, an aggregate of approximately 4,525,534 common shares, representing approximately 1.73% of the issued and outstanding common shares.

#### *Conflicts of Interest*

Other than as disclosed below, there are no existing or potential material conflicts of interest between the Company or its subsidiary and any director or officer of the Company or its subsidiary.

There are potential conflicts of interest to which the directors and officers will be subject in connection with the operations. In particular, certain of the directors serve as directors and/or officers other companies whose operations may, from time to time,

be in direct competition with the Company's operations, or with entities which may, from time to time, provide financing to, or make equity investments in, the Company's competitors.

Conflicts of interest, if any, will be subject to the procedures and remedies as provided under the OBCA. Under the OBCA, the Company's directors are required by law to act honestly and in good faith with a view to the best interests of the Company and to disclose any interest, which they may have in any project opportunity of the Company. If a conflict of interest arises at a meeting of the Board, any director in a conflict will 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 directors will primarily consider the degree of risk to which the Company may be exposed and its financial position at that time.

1. The Company pays its Chief Financial Officer by way of consulting agreement between Revive and Marrelli Support Services Inc., a company owned and/or controlled by Carmelo Marrelli. The term of the consulting agreement commenced on July 14, 2013, and shall continue until terminated by either Mr. Marrelli or the Company. Pursuant to the agreement, Mr. Marrelli is entitled to receive monthly compensation of \$1,250 per month, and incentive stock option grants on a reasonable basis, consistent with the grant of options to other grantees. In addition, Marrelli Support Services Inc. provides bookkeeping services to the Company. The amounts charged by Marrelli Support are based on what Marrelli Support Services Inc. usually charges its clients. Marrelli Support Services Inc. was owed \$2,352 as at June 30, 2020 (June 30, 2019 - \$2,390).
2. DSA Corporate Services Inc. and DSA Filing Services Limited, companies beneficially owned and/or controlled by Mr. Marrelli provides Revive with corporate secretarial and filing services. 2. DSA Corporate Services Inc. and DSA Filing Services Limited was owed \$4,603 as at June 30, 2020 (June 30, 2019 - \$1,293).

### **LEGAL PROCEEDINGS AND REGULATORY ACTIONS**

Except as disclosed below, the Company is not currently a party to any legal proceedings, nor is the Company currently contemplating any legal proceedings, which are material to its business. The Company is currently not aware of any existing or contemplated legal proceedings to which it is or was a party to, or to which any of its property is or was the subject of. The Company is not aware of any settlement agreements, penalties or sanctions that Company has entered into before a court relating to securities legislation or with a securities regulatory authority or that would be material to a reasonable investor in making an investment decision.

- The Company is involved in an ongoing dispute with a supplier over invoices in the amount of \$827,574 plus interest for which the supplier has sought arbitration. As of the date of this AIF, the Company has agreed to settle the dispute for the aggregate payment of \$500,000 of which \$250,000 will be paid in cash and the remaining \$250,000 will be satisfied through the issuance of shares in the capital of the Company.

### **INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

Except as disclosed in this AIF, no director or executive officer of the Company and, to the knowledge of the directors and executive officers of the Company, none of their respective associates or affiliates, nor any person who beneficially owns or exercises control or direction, directly or indirectly, over more than 10% of the Company's outstanding common shares, nor their respective associates or affiliates, has had any material interest, direct or indirect, in any transaction within the Company's three most recently completed financial years or in any proposed transaction which has materially affected or is reasonably expected to materially affect the Company or any of its subsidiaries on a consolidated basis.

### **RISK FACTORS**

Due to the nature of the Company's business, the legal and economic climate in which Revive operates and the present stage of development of its business, the Company may be subject to significant risks. An investment in the Company's shares should be considered highly speculative. The Company's future development and actual operating results may be very different from those expected as at the date of this AIF. There can be no certainty that the Company will be able to implement successfully its strategies. No representation is or can be made as to the future performance of the Company and there can be no assurance that the Company will achieve its objectives. An investor should carefully consider each of, and the cumulative effect of, the following risk factors.

## **Risks Related to the Company's Business and the Company's Industry**

### *Impact of COVID-19*

In December 2019, a novel strain of coronavirus ("COVID-19") emerged in Wuhan, China. Since then, it has spread to several other countries and infections have been reported around the world. Canada confirmed its first case of COVID-19 on January 25, 2020 and its first death related to COVID-19 on March 9, 2020. On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic.

In response to the outbreak, governmental authorities in Canada and internationally have introduced various recommendations and measures to try to limit the pandemic, including travel restrictions, border closures, non-essential business closures, quarantines, self-isolations, shelters-in-place and social distancing. The COVID-19 outbreak and the response of governmental authorities to try to limit it are having a significant impact on the private sector and individuals, including unprecedented business, employment and economic disruptions. The continued spread of COVID-19 nationally and globally could have an adverse impact on Revive's business, operations and financial results, including through disruptions in our cultivation and processing activities, supply chains and sales channels, as well as a deterioration of general economic conditions including a possible national or global recession. Due to the speed with which the COVID-19 situation is developing and the uncertainty of its magnitude, outcome and duration, it is not possible to estimate its impact on the Company's business, operations or financial results; however the impact could be material.

### *Regulatory, Including Healthcare Laws and Compliance Risk*

In the United States, the Company's activities are potentially subject to additional regulation by various federal, state, and local authorities in addition to the FDA, including, among others, the Centers for Medicare and Medicaid Services, other divisions of Health and Human Services, or HHS, (for example, the Office of Inspector General), the Department of Justice, and individual U.S. Attorney offices within the Department of Justice, and state and local governments.

In Canada, the Company's activities are potentially subject to additional regulation by various federal and provincial authorities in addition to Health Canada, including among others, the Ontario Cannabis Store (OCS) and publicly-mandated organizations given a provincial sales license under the Cannabis Act (Canada).

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of the Company's business activities could be subject to challenge under one or more of such laws. If the Company's operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to it, the Company may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow the Company to enter into supply contracts, including government contracts, and the curtailment or restructuring of our operations, any of which could adversely affect the Company's ability to operate its business and its results of operations. To the extent that any of the Company's products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

If clinical trials of the Company's product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, the Company's would incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of its product candidates

Before obtaining marketing approval from regulatory authorities for the sale of its product candidates, the Company must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete, and has uncertain outcomes. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials and interim results of a clinical trial do not necessarily predict final results.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. The Company does not know whether the clinical trials it may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of its product candidates in any jurisdiction. A product candidate may fail for safety or efficacy

reasons at any stage of the testing process. A major risk the Company faces is the possibility that none of its product candidates under development will successfully gain market approval from the FDA, Health Canada, or other regulatory authorities, resulting in the Company being unable to derive any commercial revenue from them after investing significant amounts of capital in multiple stages of preclinical and clinical testing.

Revive will require acceptances and/or approvals from the FDA and other foreign health regulatory bodies for conducting human clinical studies and will require approval from the FDA and equivalent organizations in other countries before any drugs can be marketed. There is no assurance that such approvals will be forthcoming. Furthermore, the exact nature of the studies these regulatory agencies will require is not known and can be changed at any time by the regulatory agencies, increasing the financing risk and potentially increasing the time to market Revive faces, which could adversely affect Revive's business, financial condition or results of operations.

In both domestic and foreign markets, the development, formulation, manufacturing, packaging, labelling, handling, distribution, import, export, licensing, sale, and storage of pharmaceuticals are affected by a body of laws, governmental regulations, administrative determinations, including those by the Canadian Food Inspection Agency and the FDA, court decisions, and similar constraints. Such laws, regulations and other constraints can exist at the federal, provincial or local levels in Canada and at all levels of government in foreign jurisdictions. There can be no assurance that Revive and Revive's partners are in compliance with all of these laws, regulations and other constraints. Revive and its partners may be required to incur significant costs to comply with such laws and regulations in the future, and such laws and regulations may have an adverse effect on the business. The failure of Revive or its partners to comply with current or future regulatory requirements could lead to the imposition of significant penalties or claims and may have a material adverse effect on the business. In addition, the adoption of new laws, regulations or other constraints or changes in the interpretations of such requirements might result in significant compliance costs or lead Revive and its partners to discontinue product development and could have an adverse effect on the business.

***The Company's product candidates contain compounds that are classified as "controlled substances" in jurisdictions outside of Canada and are classified as cannabis in Canada. Outside of Canada they will be subject to controlled substance laws and regulations; within Canada they will be subject to the Cannabis Act (Canada) and Regulations. In all jurisdictions, failure to receive necessary approvals may delay the launch of the Company's products and failure to comply with these laws and regulations may adversely affect the results of the Company's business operations***

The Company's product candidates contain substances related to the cannabis plant and are subject to the *Cannabis Act* (Canada) and *Cannabis Regulations* in Canada. As a pharmaceutical product, cannabidiol will be subject to both the Food and Drugs Act and Regulations and the *Cannabis Act* (Canada) and *Cannabis Regulations*.

In addition, since the Company's product candidates contain controlled substances/cannabis, their regulatory approval may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for our product candidates. These pressures could also limit or restrict the introduction and marketing of our product candidates. Adverse publicity from cannabis misuse or adverse side effects from cannabis or other cannabinoid products may adversely affect the commercial success or market penetration achievable for our product candidates. The nature of the Company's business attracts a high level of public and media interest, and in the event of any resultant adverse publicity, its reputation may be harmed. Furthermore, if the Company's product candidates are classified as "controlled substances", they may be subject to import/export and research restrictions that could delay or prevent the development of the Company's products in various geographical jurisdictions.

#### *Controlled Substance Legislations and Psychedelics Regulatory Risk*

The psychedelic therapy and psychopharmacological industries are new and emerging industries with substantial existing regulations and uncertainty as to future regulations. The Canadian and United States federal governments regulate drugs through the *Controlled Drugs and Substances Act* (Canada) (the "CDSA") and the *Controlled Substances Act* (21 U.S.C. § 811) (the "CSA"), respectively, which place controlled substances in a schedule. Under the CDSA, psilocybin is currently a Schedule III drug. The CDSA generally prohibits all uses of controlled substances unless an exemption is granted under section 56 of the CDSA or the regulations allow otherwise. The Minister of Health can grant exemptions under section 56 of the CDSA to use controlled substances if it is deemed to be necessary for a medical or scientific purpose or is otherwise in the public interest.

Under the CSA, psilocybin is currently a Schedule I drug. If the Company is found to be in violation of the CSA or any of the requirements of the United States Drug Enforcement Administration (the "DEA"), the DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke any registrations once granted, which could have a material adverse effect on the Company's business, operations and financial condition. In certain circumstances, violations could lead

to criminal prosecution. Certain states of the United States also maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State authorities, including boards of pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on the Company's business, operations and financial condition.

There can be no guarantee related to the future legal status of psychedelic compounds in Canada, the United States or other jurisdictions, and there is no guarantee that psilocybin-based therapeutics will ever be approved as medicines in any jurisdiction. The jurisdictional treatment of the substances would have a significant impact on the ability of the Company to continue operating or expand its business. The Company's prospects and reputation may also be impacted by developments of these laws. Furthermore, if the Company's product candidates are classified as "controlled substances", they may be subject to import/export and research restrictions that could delay or prevent the development of the Company's products in various geographical jurisdictions.

Moreover, certain of the Company's product candidates could contain substances related to the cannabis plant and are subject to the *Cannabis Act* (Canada) and Cannabis Regulations in Canada. As a pharmaceutical product, cannabidiol and psilocybin will be subject to both the *Food and Drugs Act* and Regulations, the *Cannabis Act* (Canada), Cannabis Regulations and the CDSA.

#### *Violations of Laws and Regulations Could Result in Repercussions*

In the United States, certain psychedelic drugs, including psilocybin, are classified as Schedule I drugs under the CSA and the Controlled Substances Import and Export Act (the "CSIEA") and as such, medical and recreational use is illegal under the United States federal laws. Certain other jurisdictions, including the jurisdictions in which the Company outsources certain research and development activities have similarly regulated certain psychedelic drugs. The Company's programs involving Schedule I drugs are conducted in strict compliance with the laws and regulations regarding the production, storage and use of Schedule I drugs. As such, all facilities engaged with such substances by or on behalf of the Company do so under current licenses and permits issued by appropriate federal, state and local governmental agencies. While the Company is conducting research and development of psilocybin, the Company does not have any direct or indirect involvement with the illegal selling, production or distribution of any substances in the jurisdictions in which it operates and does not intend to have any such involvement. However, a violation of any United States federal laws and regulations, such as the CSA and CSIEA, or of similar legislation in the jurisdictions in which it operates, could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings initiated by either government entities in the jurisdictions in which the Company operates, or private citizens or criminal charges. The loss of the necessary licenses and permits for Schedule I drugs could have an adverse effect on the Company's operations.

#### *Undeveloped Medical Research of Psilocybin and Psychedelic Compounds*

Research in Canada and internationally regarding the medical benefits, viability, safety, efficacy, dosing and social acceptance of psilocybin- and psychedelic-derived compounds remains in early stages. There have been relatively few clinical trials on the benefits of psilocybin and psychedelic-derived pharmaceuticals. Future research studies and clinical trials may draw opposing conclusions to those stated in this Prospectus or reach negative conclusions regarding the medical benefits, viability, safety, efficacy and dosing or other facts and perceptions related to psilocybin and psychedelic-derived pharmaceuticals, which could have a material adverse effect on the demand for the Company's product candidates and technologies with the potential to lead to a material adverse effect on the Company's business, financial condition and results of operations.

#### *Manufacturing, Pharmaceutical Development and Marketing Capability*

The Company has no, and does not expect to have any, in-house manufacturing, product development, or marketing capability. To be successful, a product must be manufactured and packaged in commercial quantities in compliance with regulatory requirements and in reasonable time frames and at accepted costs. The Company intends to contract with third parties to develop its products. No assurance can be given that the Company or its suppliers will be able to meet the supply requirements of the Company in respect of the product development or commercial sales. Production of therapeutic products may require raw materials for which the sources and amount of supply are limited, or may be hindered by quality or scheduling issues in respect of the third party suppliers over which the Company has limited control. An inability to obtain adequate supplies of raw materials could significantly delay the development, regulatory approval and marketing of a product. The Company has limited in-house personnel to internally manage all aspects of product development, including the management of multi-center clinical trials. The Company is significantly reliant on third party consultants and contractors to provide the requisite advice and management. There can be no assurance that the clinical trials and product development will not encounter delays which could adversely affect

prospects for the Company's success.

To be successful, an approved product must also be successfully marketed. The market for a product developed by the Company may be large and require substantial sales and marketing capability. At the present time, Revive does not have any internal capability to market products or technologies. The Company intends to enter into one or more strategic partnerships or collaborative arrangements with pharmaceutical or cannabis companies or other companies with marketing and distribution expertise to address this need. If necessary, the Company will establish arrangements with various partners for geographical areas. There can be no assurance that the Company can market, or can enter into a satisfactory arrangement with a third party to market a product in a manner that would assure its acceptance in the market place. However, if a satisfactory arrangement with a third party to market and/or distribute a product is obtained, then the Company will be dependent on the corporate collaborator(s) who may not devote sufficient time, resources, and attention to the Company's programs, which may hinder efforts to market the products. Should the Company not establish marketing and distribution strategic partnerships and collaborative arrangements on acceptable terms, and undertake some or all of those functions, the Company will require significant additional human and financial resources and expertise to undertake these activities, the availability of which is not guaranteed.

The Company will rely on third parties for the timely supply of raw materials, equipment, contract manufacturing, and formulation or packaging services. Although the Company intends to manage these third party relationships to ensure continuity and quality, some events beyond the Company's control could result in complete or partial failure of these goods and services. Any such failure could have a material adverse effect on the financial conditions and result of operations of the Company.

The Company will rely on contract manufacturing organizations ("CMOs") to manufacture our product candidates for preclinical studies and clinical trials and rely on CMOs for manufacturing, filling, packaging, storing, and shipping of drug products in compliance with current good manufacturing practice, or cGMP, regulations applicable to our products. The FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with cGMP regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. If our CMOs increase their prices or fail to meet our quality standards, or those of regulatory agencies such as the FDA, and cannot be replaced by other acceptable CMOs, our ability to obtain regulatory approval for and commercialize our product candidates may be materially adversely affected.

#### *Rapidly Changing Industry*

The market for Revive's products and services is characterized by rapid intellectual property advances, changes in customer requirements, changes in protocols and evolving industry standards. If the Company is unable to develop enhancements to its existing products and services or acceptable new products and services that keep pace with rapidly changing developments, its products and services may become obsolete, less marketable and less competitive and Revive's business will be harmed.

#### *Regulatory Approval Licenses and Permits*

Revive may be required to obtain and maintain certain permits, licenses, and approvals in the jurisdictions where its products or technologies are being researched, developed, or commercialized. There can be no assurance that the Company will be able to obtain or maintain any necessary licenses, permits, or approvals. Any material delay or inability to receive these items is likely to delay and/or inhibit the Company's ability to conduct its business, and would have an adverse effect on its business, financial condition, and results of operations.

#### *Raw Material and Product Supply*

Raw materials and supplies are generally available in quantities to meet the needs of the Company's business. The Company will be dependent on third-party manufacturers for the products and technologies that it markets. An inability to obtain raw materials or product supply could have a material adverse impact on the Company's business, financial condition, and results of operations.

#### *The lack of product for commercialization*

If the Company cannot successfully develop, manufacture and distribute its products, or if the Company experiences difficulties in the development process, such as capacity constraints, quality control problems or other disruptions, the Company may not be able to develop market-ready commercial products at acceptable costs, which would adversely affect the Company's ability to effectively enter the market. A failure by the Company to achieve a low cost structure through economies of scale or



improvements in cultivation and manufacturing processes would have a material adverse effect on the Company's commercialization plans and the Company's business, prospects, results of operations and financial condition.

#### *Controlled Substance Legislations*

Most countries are parties to *the Single Convention on Narcotic Drugs 1961*, which governs international trade and domestic control of narcotic substances, including cannabis. Countries may interpret/implement their treaty obligations in a way that creates a legal obstacle to our obtaining marketing approval for the Company's product candidates in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit the Company's product candidates to be marketed, or achieving such amendments to the laws and regulations may take a prolonged period of time.

#### *Competition*

The pharmaceutical industry is highly competitive and subject to rapid change. The industry continues to expand and evolve as an increasing number of competitors and potential competitors enter the market. Many of these competitors and potential competitors have substantially greater financial, technological, managerial and research and development resources and experience than the Company has. Some of these competitors and potential competitors have more experience than the Company has in the development of pharmaceutical products, including validation procedures and regulatory matters. Other companies researching in the same disease areas may develop products that are competitive or superior to the Company's product candidates. Other companies working in cannabinoid research may develop products targeting the same diseases that the Company is focused on that are competitive or superior to its product candidates. In addition, there are non-FDA approved cannabis/cannabinoid preparations being made available from companies in the medical marijuana industry, which may be competitive to the Company's products. If the Company is unable to compete successfully, its commercial opportunities will be reduced and its business, results of operations and financial conditions may be materially harmed.

#### *Unproven Market for Products and Technologies*

The Company believes that the anticipated market for its potential products and technologies will continue to exist and expand. These assumptions may prove to be incorrect for a variety of reasons, including competition from other products and the degree of commercial viability of the potential product.

Even when product development is successful and regulatory approval has been obtained, the Company's ability to generate significant revenue depends on the acceptance of its products by physicians and patients. The Company cannot be sure that its pharmaceutical cannabinoid product candidates will achieve the expected market acceptance and revenue if and when they obtain the requisite regulatory approvals. The market acceptance of any product depends on a number of factors, including the indication statement and warnings approved by regulatory authorities on the product label, continued demonstration of efficacy and safety in commercial use, physicians' willingness to prescribe the product, reimbursement from third-party payers such as government health care systems and insurance companies, the price of the product, the nature of any post-approval risk management plans mandated by regulatory authorities, competition, and marketing and distribution support. Any actors preventing or limiting the market acceptance of the Company's products could have a material adverse effect on our business, results of operations, and financial condition.

Because the cannabis industry is in a nascent stage with uncertain boundaries, there is a lack of information about comparable companies available for potential investors to review in deciding about whether to invest in the Company and, few, if any, established companies whose business model the Company can follow or upon whose success the Company can build. Accordingly, investors will have to rely on their own estimates in deciding about whether to invest in the Company. There can be no assurance that the Company's estimates are accurate or that the market size is sufficiently large for its business to grow as projected, which may negatively impact its financial results.

#### *Commercialized products*

The Company is yet to bring a product to market. Even if the Company obtains regulatory approval for a product, the Company's future success will still depend on its ability to successfully commercialize our products, which depends on a number of factors beyond the Company's control, including the willingness of physicians to prescribe its products to patients, payers' willingness and ability to pay for the drug, the level of pricing achieved, patients' response to our products, the ability of its marketing partners to generate sales and our ability to manufacture products on a cost-effective and efficient basis. The Company is we are not successful in the commercialization of our products, its business, results of operations, and financial condition may be harmed.

### *Product liability once in the production phase*

As a possible manufacturer and distributor of products designed to be ingested by humans, once the Company is in the production phase, it faces an inherent risk of exposure to product liability claims, regulatory action and litigation if its products are alleged to have caused significant loss or injury. In addition, the manufacture and sale of cannabis products involve the risk of injury to consumers due to tampering by unauthorized third parties or product contamination. Previously unknown adverse reactions resulting from human consumption of cannabis products alone or in combination with other medications or substances could occur. The Company may be subject to various product liability claims, including, among others, that the products produced by the Company caused injury or illness, include inadequate instructions for use or include inadequate warnings concerning possible side effects or interactions with other substances. A product liability claim or regulatory action against the Company could result in increased costs, could adversely affect the Company's reputation with its clients and consumers generally, and could have a material adverse effect on the business, financial condition and operating results of the Company. There can be no assurances that the Company will be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities. Such insurance is expensive and may not be available in the future on acceptable terms, or at all. The inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of products.

### *Preclinical Studies*

The Company relies and will continue to rely on third parties to conduct a significant portion of clinical development and planned preclinical activities. Preclinical activities include in vivo studies providing access to specific disease models, pharmacology and toxicology studies, and assay development. Clinical development activities include trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in the Company's relationship with third parties, or if the Company is unable to provide quality services in a timely manner and at a feasible cost, any active development programs could face delays. Further, if any of these third parties fails to perform as expected or if their work fails to meet regulatory requirements, testing could be delayed, cancelled or rendered ineffective.

### *Pre-Clinical Studies and Initial Clinical Trials are not Necessarily Predictive of Future Results and Other Risks of Clinical Trials*

Before obtaining marketing approval from regulatory authorities for the sale of its product candidates, the Company must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete, and has uncertain outcomes. Pre-clinical studies and human clinical studies (Phase 1, Phase 2 and Phase 3) and clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the side effects of product candidates at various doses and schedules. Success in pre-clinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. Favourable results in early trials may not be repeated in later trials. A number of companies in the life sciences industry have suffered significant setbacks in advanced clinical trials, even after positive results in earlier trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit, or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated, or terminated. Any pre-clinical data and the clinical results obtained for our technologies may not predict results from studies in larger numbers of subjects drawn from more diverse populations or in the commercial setting, and also may not predict the ability of our products to achieve their intended goals, or to do so safely.

If clinical trials of the Company's product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, the Company would incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of its product candidates.

The Company does not know whether the clinical trials it may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of its product candidates in any jurisdiction. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk the Company faces is the possibility that none of its product candidates under development will successfully gain market approval from the FDA, Health Canada, or other regulatory authorities, resulting in the Company being unable to derive any commercial revenue from them after investing significant amounts of capital in multiple stages of preclinical and clinical testing.

The Company will require acceptances and/or approvals from the FDA and other foreign health regulatory bodies for conducting

human clinical studies and will require approval from the FDA and equivalent organizations in other countries before any drugs can be marketed. There is no assurance that such approvals will be forthcoming. Furthermore, the exact nature of the studies these regulatory agencies will require is not known and can be changed at any time by the regulatory agencies, increasing the financing risk and potentially increasing the time to market the Company faces, which could adversely affect the Company's business, financial condition or results of operations.

#### *Negative Results from Clinical Trials*

From time to time, studies or clinical trials on various aspects of biopharmaceutical products are conducted by academic researchers, competitors or others. The results of these studies or trials, when published, may have a significant effect on the market for the biopharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials or adverse safety events related to the Company's product candidates, or the therapeutic areas in which the Company's product candidates compete, could adversely affect the share price and ability to finance future development of the Company's product candidates, and the business and financial results could be materially and adversely affected.

### **Risks Related to Intellectual Property and Litigation**

#### *Intellectual Property and Licenses*

The Company's success is heavily dependent on the Company's intangible properties and technologies, and will depend in part on its ability to protect and maintain its intellectual property rights. Moreover, the Company could potentially incur substantial legal costs in defending legal actions which allege patent infringement or by instituting patent infringement suits against others. The Company's commercial success also depends on the Company not infringing patents or proprietary rights of others. There can be no assurance that the Company will be able to maintain such licenses that it may require to conduct its business or that such licenses have been obtained at a reasonable cost. Furthermore, there can be no assurance that the Company will be able to remain in compliance with any such licenses. Consequently, there may be a risk that such licenses may be withdrawn with no compensation or penalties to the Company.

#### *Risks Related to Potential Inability to Protect Intellectual Property*

Revive's success is heavily dependent upon the Company's intangible property and technologies. The Company licenses certain of its product and technology from third parties and there can be no assurance that the Company will be able to continue licensing these rights on a continuous basis. The Company relies upon copyrights, trade secrets, unpatented proprietary know-how, and continuing technology innovation to protect the product and technology that the Company considers important to the development of its business. The Company relies on various methods to protect its proprietary rights, including confidentiality agreements with its consultants, service providers, and management that contain terms and conditions prohibiting unauthorized use and disclosure of the Company's confidential information. However, despite the Company's efforts to protect its intangible property rights, unauthorized parties may attempt to copy or replicate the Company's product or technology. There can be no assurances that the steps taken by the Company to protect its product and technology will be adequate to prevent misappropriation or independent third-party development of its product and technology. It is likely that other companies can duplicate a production process similar to the Company's. To the extent that any of the above could occur, the Company's revenue could be negatively affected, and in the future, the Company may have to litigate to enforce its intangible property rights, which could result in substantial costs and divert the Company management's attention and the Company's resources.

#### *Protection of the Company's Intellectual Property*

The Company's success depends a significant degree upon its ability to develop, maintain and protect proprietary products and technologies. The Company may file patent applications in the U.S., Canada, Europe, and selectively in other foreign countries as part of its strategy to protect its proprietary products and technologies. However, patents provide only limited protection of the Company's intellectual property. The assertion of patent protection involves complex legal and factual determinations and is therefore uncertain and expensive. Revive cannot provide assurances that patents will be granted with respect to any of its pending patent applications, that the scope of any of its patents will be sufficiently broad to offer meaningful protection, or that it will develop additional proprietary technologies that are patentable. This could result in the Company's patent rights failing to create an effective competitive barrier. Losing a significant patent or failing to get a patent to issue from a pending patent application that the Company considers significant could have a material adverse effect on its business. The laws governing the scope of patent coverage in various countries continue to evolve. The laws of some foreign countries may not protect the Company's intellectual property rights to the same extent as the laws of Canada and the U.S. The Company holds patents only in selected countries. Therefore, third parties may be able to replicate technologies covered by the Company's patents in countries

in which it does not have patent protection.

There can be no assurances that the steps taken by the Company to protect its intangible property, technology and information will be adequate to prevent misappropriation or independent third-party development of the Company's intangible property, technology or processes. It is likely that other companies can duplicate a production process similar to Revive. Other companies may also be able to materially duplicate the Company's proprietary plant strains. To the extent that any of the above would occur, revenue could be negatively affected, and in the future, the Company may have to litigate to enforce its intangible property rights, which could result in substantial costs and divert management's attention and other resources.

Revive's ability to successfully implement its business plan depends in part on its ability to obtain, maintain and build brand recognition using its trademarks, service marks, trade dress, domain names and other intellectual property rights, including the Company's names and logos. If the Company's efforts to protect its intellectual property are unsuccessful or inadequate, or if any third party misappropriates or infringes on its intellectual property, the value of its brands may be harmed, which could have a material adverse effect Revive's business and might prevent its brands from achieving or maintaining market acceptance.

The Company may be unable to obtain registrations for its intellectual property rights for various reasons, including refusal by regulatory authorities to register trademarks or other intellectual property protections, prior registrations of which it is not aware, or it may encounter claims from prior users of similar intellectual property in areas where it operates or intends to conduct operations. This could harm its image, brand or competitive position and cause the Company to incur significant penalties and costs.

#### *Changes to Patent Law*

Important legal issues remain to be resolved as to the extent and scope of available patent protection for biopharmaceutical and technological processes in Canada, the United States and other important markets such as Europe. As such, litigation or administrative proceedings may be necessary to determine the validity, scope and ownership of certain of the Company's and others' proprietary rights. Any such litigation or proceeding may result in a significant commitment of resources in the future and could force the Company to do one or more of the following: cease using any of its future products that incorporate a challenged intellectual property, which would adversely affect its revenue; obtain a license or other rights from the holder of the intellectual property right alleged to have been infringed or otherwise violated, which license may not be available on reasonable terms, if at all; and redesign its future products to avoid infringing or violating the intellectual property rights of third parties, which may be time-consuming or impossible to do. In addition, changes in patent laws in Canada and other countries may result in allowing others to use the Company's discoveries or develop and commercialize the Company's products. The Company cannot provide assurance that the patents it obtains will afford it significant commercial protection.

#### *Risk of Third Party Claims for Infringement*

A third party may claim that the Company has infringed such third party's rights or may challenge the right of the Company to its intellectual property. In such event, the Company will undertake a review to determine what, if any, action should be taken with respect to such claim. Any claim, whether or not with merit, could be time consuming to evaluate, result in costly litigation, cause delays in the operations of the Company or the development of its intellectual property or require the Company to enter into licensing arrangements that may require the payment of a license fee or royalties to the owner of the intellectual property. Such royalty or licensing arrangements, if required, may not be available on terms acceptable to the Company.

#### *Trade Secrets may be Difficult to Protect*

Revive's success depends upon the skills, knowledge and experience of its scientific and technical personnel, consultants and advisors, as well as contractors. Because the Company operates in a highly competitive industry, it relies in part on trade secrets to protect its proprietary products and processes; however, trade secrets are difficult to protect. Revive enters into confidentiality or non-disclosure agreements with its corporate partners, employees, consultants, outside scientific collaborators, developers and other advisors. These agreements generally require that the receiving party keep confidential, and not disclose to third parties, confidential information developed by the receiving party or made known to the receiving party by the Company during the course of the receiving party's relationship with the Corporation. These agreements also generally provide that inventions conceived by the receiving party in the course of rendering services to Revive will be its exclusive property, and the Company enters into assignment agreements to perfect its rights.

These confidentiality, inventions and assignment agreements, where in place, may be breached and may not effectively assign intellectual property rights to the Company. Revive's trade secrets also could be independently discovered by competitors, in

which case the Company would not be able to prevent the use of such trade secrets by its competitors. The enforcement of a claim alleging that a party illegally obtained and was using the Company's trade secrets could be difficult, expensive and time consuming and the outcome could be unpredictable. The failure to obtain or maintain meaningful trade secret protection could adversely affect the Company's competitive position.

## **Other Risks**

### *Going-Concern Risk*

The Company's financial statements have been prepared on a going concern basis under which the Company is considered to be able to realize its assets and satisfy its liabilities in the ordinary course of business. Revive's future operations are dependent upon the identification and successful completion of equity or debt financing and the achievement of profitable operations at an indeterminate time in the future. There can be no assurances that the Company will be successful in completing additional equity or debt financing or in achieving profitability. The financial statements do not give effect to any adjustments relating to the carrying values and classification of assets and liabilities that would be necessary should the Company be unable to continue as a going concern.

### *History of Operating Losses*

To date, Revive has a history of operating losses and may not achieve or sustain profitability. Since incorporation, Revive has accumulated net losses and expects such losses to continue as it commences product, clinical, and commercial development for its products and its technologies. Management expects to continue to incur substantial operating losses unless and until such time as sales generate sufficient revenues to fund continuing operations and may not be able to sustain or increase profitability and failure to do so could adversely affect the Company's business, including its ability to raise additional funds.

### *Negative Operating Cash Flow*

The Company's business has incurred losses since its inception. Although the Company expects to become profitable, there is no guarantee that will happen, and the Company may never become profitable. The Company currently has a negative operating cash flow and may continue to have a negative operating cash flow for the foreseeable future. To date, the Company has not generated any revenues and a large portion of the Company's expenses are fixed, including expenses related to facilities, equipment, contractual commitments and personnel. As a result, the Company expects for its net losses from operations to improve. The Company's ability to generate additional revenues and potential to become profitable will depend largely on its ability to manufacture and market its products and services. There can be no assurance that any such events will occur or that the Company will ever become profitable. Even if the Company does achieve profitability, the Company cannot predict the level of such profitability. If the Company sustains losses over an extended period of time, the Company may be unable to continue its business.

### *Need for Additional Capital and Access to Capital Markets*

The Company will need additional capital to complete its current research, development, and commercial programs. It is anticipated that future research, additional pre-clinical and toxicology studies, manufacturing, and marketing initiatives, including that to prepare for market approval and successful product market launch, will require additional funds. Further financing may dilute the current holdings of shareholders and may thereby result in a loss for shareholders. There can be no assurance that the Company will be able to obtain adequate financing, or financing on terms that are reasonable or acceptable for these or other purposes, or to fulfill the Company's obligations under the various license agreements. Failure to obtain such additional financing could result in delay or indefinite postponement of further research and development of the Company's products and technologies with the possible loss of license rights to these products and technologies.

### *Share Volatile*

The market prices for securities of biotechnology companies, including the Company's, have historically been volatile. A number of factors could influence the volatility in the trading price of Revive's Common Shares, including changes in the economy or in the financial markets, industry related developments, the results of product development and commercialization, changes in government regulations, and developments concerning proprietary rights, litigation and cash flow. Revive's quarterly losses may vary because of the timing of costs for clinical trials, manufacturing and preclinical studies. Also, the reporting of clinical data or the lack thereof, adverse safety events involving the Company's products and public rumors about such events could cause its share price to decline or experience periods of volatility. Each of these factors could lead to increased volatility in the market

price of the Company's Common Shares. In addition, changes in the market prices of the securities of Revive's competitors may also lead to fluctuations in the trading price of the Company's Common Shares.

#### *Dilution and Future Issuances of Shares*

The Company may sell additional equity securities in future offerings, including through the sale of securities convertible into equity securities, to finance operations, acquisitions or projects, and issue additional Common Shares if outstanding securities are converted into Common Shares, which may result in dilution.

The Company's board of directors will have the authority to authorize certain offers and sales of additional securities without the vote of, or prior notice to, shareholders. Based on the need for additional capital to fund expected expenditures and growth, it is likely that the Company will issue additional securities to provide such capital. Sales of substantial amounts of securities, or the availability of such securities for sale, as well as the issuance of substantial amounts of Common Shares upon conversion or exchange of outstanding convertible or exchangeable securities, could adversely affect the prevailing market prices for securities and dilute investors' earnings per share. A decline in the future market prices of the Company's securities could impair its ability to raise additional capital through the sale of securities should it desire to do so.

In the past, following periods of volatility in the market price of a company's securities, shareholders have instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the Company's profitability and reputation. The market price for the Common Shares may also be affected by the Company's ability to meet or exceed expectations of analysts or investors. Any failure to meet these expectations, even if minor, may have a material adverse effect on the market price of the Common Shares.

#### *Requirement to Generate Cash Flow for Financial Obligations*

Revive currently has negative operating cash flows. The Company's ability to generate sufficient cash flow from operations to make scheduled payments to the Company's contractors, service providers, and merchants will depend on future financial performance, which will be affected by a range of economic, competitive, regulatory, legislative, and business factors, many of which are outside of the Company's control. If the Company does not generate sufficient cash flow from operations to satisfy its contractual obligations, the Company may have to undertake alternative financing plans. The Company's inability to generate sufficient cash flow from operations or undertake alternative financing plans would have an adverse effect on the Company's business, financial condition, and results or operations, as well as its ability to satisfy the Company's contractual obligations. Any failure to meet the Company's financial obligations could result in termination of key contracts, which could harm the Company's ability to provide its products and technologies.

#### *Early Stage Development*

Revive has not begun to market any product or to generate revenues. The Company expects to spend a significant amount of capital to fund research and development and on further laboratory, animal studies and clinical trials. As a result, the Company expects that its operating expenses will increase significantly and, consequently, it will need to generate significant revenues to become profitable. Even if the Company does become profitable, it may not be able to sustain or increase profitability on a quarterly or annual basis. The Company cannot predict when, if ever, it will be profitable. There can be no assurances that the intellectual property of Revive, or other products or technologies it may acquire, will meet applicable regulatory standards, obtain required regulatory approvals, be capable of being produced in commercial quantities at reasonable costs, or be successfully marketed. The Company will be undertaking additional laboratory, animal studies, and clinical studies with respect to the intellectual property of Revive, and there can be no assurance that the results from such studies or trials will result in a commercially viable product or will not identify unwanted side effects.

#### *Ability to Manage Growth*

Recent rapid growth in all areas of Revive's business has placed, and is expected to continue to place, a significant strain on its managerial, operational and technical resources. The Company expects operating expenses and staffing levels to increase in the future. To manage such growth, the Company must expand its operation and technical capabilities and manage its employee base while effectively administering multiple relationships with various third parties. There can be no assurance that the Company will be able to manage its expanding operations effectively. Any failure to implement cohesive management and operating systems, to add resources on a cost-effective basis or to properly manage the Company's expansion could have a material adverse effect on the Company's business and results of operations.

### *Effectiveness of Disclosure Controls and Procedures*

The Company's disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by the Company in reports it files or submits under applicable securities laws is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified under applicable securities laws. The Company believes that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in the Company's control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

### *Effectiveness of Internal Controls*

Effective internal controls are necessary to provide reliable financial reports and prevent fraud. If there is a failure to maintain an effective system of internal controls, the Company might not be able to report financial results accurately or prevent fraud; and in that case, shareholders could lose confidence in the Company's financial reporting, which would harm the business and could negatively impact the price of the Common Shares. While the Company believes that it will have sufficient personnel and review procedures to maintain an effective system of internal controls, no assurance can be provided that potential material weaknesses in internal control could arise. Even if it is concluded that the internal control over financial reporting provides reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with International Financial Reporting Standards, as issued by the International Accounting Standards Board, because of its inherent limitations, internal control over financial reporting may not prevent or detect fraud or misstatements. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm results of operations or cause a failure to meet future reporting obligations.

### *Legal Proceedings*

In the course of the Company's business, the Company may from time to time have access to confidential or proprietary information of third parties, and these parties could bring a claim against the Company asserting that it has misappropriated their technologies and had improperly incorporated such technologies into the Company's products. Due to these factors, there remains a constant risk of intellectual property litigation affecting the Company's business. Additionally, Revive faces litigation risks arising from its use of independent contractors and research collaborations to advance research and development of its product pipeline candidates. The Company may be made a party to litigation involving intellectual property, commercial disputes, and other matters, and such actions, if determined adversely, could have a material adverse effect on Revive.

The Company is a party to an arbitration proceeding and cannot predict the outcome of this proceeding (including whether any arbitration award could have a material adverse effect on the Company). See "*Legal Proceedings and Regulatory Actions*".

*The Company will be reliant on information technology systems and may be subject to damaging cyber-attacks.*

The Company has entered into agreements with third parties for hardware, software, telecommunications and other information technology ("IT") services in connection with its operations. The Company's operations depend, in part, on how well it protects networks, equipment, IT systems and software against damage from a number of threats, including, but not limited to, cable cuts, natural disasters, intentional damage and destruction, fire, power loss, hacking, computer viruses, vandalism and theft. The Company's operations also depend on the timely maintenance, upgrade and replacement of networks, equipment, IT systems and software, as well as preemptive expenses to mitigate the risks of failures. Any of these and other events could result in information system failures, delays and/or increase in capital expenses. The failure of information systems or a component of information systems could, depending on the nature of any such failure, adversely impact the Company's reputation and results of operations.

The Company has not experienced any material losses to date relating to cyber-attacks or other information security breaches, but there can be no assurance that the Company will not incur such losses in the future. The Company's risk and exposure to these matters cannot be fully mitigated because of, among other things, the evolving nature of these threats. As a result, cyber security and the continued development and enhancement of controls, processes and practices designed to protect systems, computers, software, data and networks from attack, damage or unauthorized access is a priority. As cyber threats continue to

evolve, the Company may be required to expend additional resources to continue to modify or enhance protective measures or to investigate and remediate any security vulnerabilities.

#### *Effectiveness and Efficiency of Advertising and Promotional Expenditures*

Revive's future growth and profitability will depend on the effectiveness and efficiency of advertising and promotional expenditures, including the Company's ability to (i) create greater awareness of its products; (ii) determine the appropriate creative message and media mix for future advertising expenditures; and (iii) effectively manage advertising and promotional costs in order to maintain acceptable operating margins. There can be no assurance that advertising and promotional expenditures will result in revenues in the future or will generate awareness of the Company's technologies or products. In addition, no assurance can be given that the Company will be able to manage the Company's advertising and promotional expenditures on a cost-effective basis.

#### *Lack of Diversity*

Larger companies have the ability to manage their risk through diversification. However, Revive currently lacks diversification in terms of the nature of its business. As a result, Revive could potentially be more impacted by factors affecting the pharmaceutical and cannabis industry in general than would be the case if the business was more diversified. Currently, Revive's primary focus is the development and commercialization of its cannabinoid-based products and technologies. Accordingly, Revive is dependent on its ability to develop and commercialize its products and technologies and any factor that materially adversely affects its ability to do so may have a material adverse effect on Revive's financial condition and results of operations.

#### *Key Personnel Risk*

Revive's success and future growth will depend, to a significant degree, on the continued efforts of the Company's directors and officers to develop the business and manage operations and on their ability to attract and retain key technical, scientific, sales and marketing staff or consultants. The loss of any key person or the inability to attract and retain new key persons could have a material adverse effect on the Company's business. Competition for qualified technical, scientific, sales and marketing staff, as well as officers and directors can be intense and no assurance can be provided that the Company will be able to attract or retain key personnel in the future. The Company's inability to retain and attract the necessary personnel could materially adversely affect the Company's business and financial results from operations.

#### *Conflict of Interest*

Certain of the directors of the Company are also directors and officers of other companies, some of which may be in the pharmaceutical sector, and conflicts of interest may arise between their duties as directors of the Company and as officers and directors of such other companies. Such conflicts must be disclosed in accordance with, and are subject to such other procedures and remedies as apply under the applicable corporate statute.

#### *Failure to comply with the U.S. Foreign Corrupt Practices Act ("FCPA"), the Canadian Corruption of Foreign Public Officials Act ("CFPOA")*

The FCPA and the CFPOA, as well as any other applicable domestic or foreign anti-corruption or anti-bribery laws to which the Company is or may become subject generally prohibit corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity and requires companies to maintain accurate books and records and internal controls, including at foreign-controlled subsidiaries.

Compliance with these anti-corruption laws and anti-bribery laws may be expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, these laws present particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and physicians and other hospital employees are considered to be foreign officials. Certain payments by other companies to hospitals in connection with clinical trials and other work have been deemed to be improper payments to governmental officials and have led to FCPA enforcement actions.

The Company's internal control policies and procedures may not protect it from reckless or negligent acts committed by the Company's employees, future distributors, licensees or agents. The Company can make no assurance that they will not engage in prohibited conduct, and the Company may be held liable for their acts under applicable anti-corruption and anti-bribery laws. Noncompliance with these laws could subject the Company to investigations, sanctions, settlements, prosecution, other



enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension or debarment from contracting with certain persons, the loss of export privileges, whistleblower complaints, reputational harm, adverse media coverage, and other collateral consequences. Any investigations, actions or sanctions or other previously mentioned harm could have a material negative effect on the Company's business, operating results and financial condition.

#### *Use of Future Profits*

The Company will not pay dividends on the issued and outstanding Common Shares in the foreseeable future. If the Company generates any future earnings, such cash resources will be retained to finance further growth and current operations. The board of directors will determine if and when dividends should be declared and paid in the future based on the Company's financial position and other factors relevant at the particular time. Until the Company pays dividends, which it may never do, a shareholder will not be able to receive a return on his or her investment in the Common Shares unless such Common Shares are sold. In such event, a shareholder may only be able to sell his, her or its Common Shares at a price less than the price such shareholder originally paid for them, which could result in a significant loss of such shareholder's investment.

#### *Pursuant of Other Business Opportunities*

From time to time, the Company may pursue opportunities for further research and development of other products. The Company's success in these activities will depend on its ability to identify suitable technical experts, market needs, and effectively execute any such research and development opportunities. Any research and development would be accompanied by risks as a result of the use of business efforts and funds. In the event that the Company chooses to raise debt capital to finance any such research or development opportunities, its leverage will be increased. There can be no assurance that the Company would be successful in overcoming these risks or any other problems encountered in connection with any research or development opportunities.

#### *External Events*

The Company may be impacted by business interruptions resulting from pandemics and public health emergencies, including those related to COVID-19 coronavirus, geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires. An outbreak of infectious disease, a pandemic or a similar public health threat, such as the recent outbreak of the novel coronavirus known as COVID-19, or a fear of any of the foregoing, could adversely impact the Company by causing operating, manufacturing supply chain, clinical trial and project development delays and disruptions, labour shortages, travel and shipping disruption and shutdowns (including as a result of government regulation and prevention measures). It is unknown whether and how the Company may be affected if such an epidemic persists for an extended period of time. The Company may incur expenses or delays relating to such events outside of its control, which could have a material adverse impact on its business, operating results and financial condition.

#### *Difficulties with Forecasts*

The Company must rely largely on its own market research to forecast sales as detailed forecasts are not generally obtainable from other sources at this early stage of the medical marijuana industry in Canada. A failure in the demand for its products and services to materialize as a result of competition, technological change or other factors could have a material adverse effect on the business, results of operations and financial condition of the Company.

#### *Fluctuations in Foreign Currency Exchange Rates*

Revive is subject to foreign currency risk. The strengthening or weakening of the Canadian or U.S. dollar versus other currencies will impact the translation of the Company's expenses and net revenues generated in these foreign currencies into Canadian and US dollars. The Company imports certain products from foreign countries, and so may become forced to pay higher rates for these products as a result of the weakening of the Canadian or U.S. dollar.

### **TRANSFER AGENT AND REGISTRAR**

Computershare Trust Company of Canada of Vancouver, British Columbia is the Transfer Agent and Registrar for the common shares.

## MATERIAL CONTRACTS

The Company has no material contracts, other than contracts entered into in the ordinary course of business, that were entered into during the financial year ended June 30, 2020 or that were entered into before the financial year ended June 30, 2020 that are still in effect, other than:

- (i) Joint venture partnership agreement with Herman Holdings Ltd. for the development, production, distribution, marketing and sale of cannabis derivative products for the Canadian recreational cannabis market.
- (ii) Supply and collaboration agreement with Red Light Holland Financing Inc. whereby the Company will acquire a consistent strain of truffles from Red Light Holland Financing Inc. for the sole purpose of undertaking research and development on the suitability and implementation of the Company's novel cannabinoid delivery technology with respect to the truffles and its extracts.
- (iii) Share exchange agreement whereby the Company acquired all of the issued and outstanding securities in the capital of Psilocin Pharma Corp.
- (iv) Agency agreement with Hampton Securities Limited with respect to the offering of up to an aggregate of 50,000,000 units for aggregate gross proceeds of \$2,500,000.
- (v) Service agreement with Pharm-Olam LLC pursuant to which Pharm-Olam LLC will serve as the Company's Contract Research Organization to advance the future clinical study for Bucillamine in the treatment of infectious diseases, including the coronavirus disease ("COVID-19").
- (vi) Service agreement with Novotech pursuant to which Novotech will serve as the Company's Contract Research Organization in the Asia-Pacific region to advance the future clinical study for Bucillamine in the Asia-Pacific countries.
- (vii) Service agreement with Complete Phytochemical Solutions, LLC. for the advancement of the Company's research and development initiatives of psilocybin-based products for the pharmaceutical market.
- (viii) Partnership agreement with the University of Wisconsin-Madison for the evaluation of novel formulations and drug delivery technology focused on psilocybin-based pharmaceuticals.
- (ix) Sponsored research partnership agreement with the University of Wisconsin-Madison for the evaluation of novel formulations of psilocybin and a Phase 1 clinical study investigating the therapeutic application of psilocybin for an undisclosed addiction use disorder.

## INTERESTS OF EXPERTS

The Company's auditor is Clearhouse LLP ("Clearhouse").

Clearhouse has prepared an independent auditor's report dated October 28, 2020 in respect of the Company's consolidated financial statements with accompanying notes as at June 30, 2020 and 2019 and for the years ended June 30, 2020 and 2019. Clearhouse has advised that it is independent with respect to the Company within the meaning of the Rules of Professional Conduct of the Institute of Chartered Professional Accountants of Ontario.

## AUDIT COMMITTEE

### *Audit Committee Charter*

The text of the Audit Committee's Charter in effect as of the date hereof is attached hereto as Appendix "A".

### *Composition of the Audit Committee*

The current members of the Audit Committee are Andrew Lindzon, William Jackson and Michael Frank. All members of the Audit Committee for the year ended June 30, 2020 were financially literate. Messieurs Lindzon and Jackson are independent members of the committee while Mr. Frank is deemed to be non-independent as he is the Chief Executive Officer of the

Company.

To be considered independent, a member of the Audit Committee must not have any direct or indirect “material relationship” with the Company. A “material relationship” is a relationship which could, in the view of the Board, be reasonably expected to interfere with the exercise of a member’s independent judgment.

To be considered financially literate, a member of the Audit Committee must have the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Company’s financial statements.

#### *Relevant Education and Experience*

Please see “Directors and Officers - Biographies of Directors” in this AIF for a description of the relevant education and experience of the members of the Audit Committee.

#### *External Auditor Service Fees*

The following table sets forth the fees paid to MNP, the external auditor of the Company, for services rendered for financial years ended June 30 2020 and 2019:

<b>Financial Year Ending</b>	<b>Audit Fees</b>	<b>Audit Related Fees</b>	<b>Tax Fees</b>	<b>All Other Fees</b>
June 30, 2020	\$27,000	-	-	-
June 30, 2019	\$25,000	\$700	\$3,300	-

Audit Fees - Audit fees were paid for professional services rendered by the auditor for the audit of the annual financial statements of the Company and its wholly owned subsidiaries and services provided in connection with statutory and regulatory filings or engagements.

Audit-Related Fees - Audit-related fees include fees paid to the Company’s auditor for attestation services, quarterly review, services provided in connection with the Company’s offering of convertible unsecured subordinated debentures and other accounting and reporting consultations. In addition, audit-related fees include the cost of translation of various continuous disclosure documents of the Company.

Tax Fees - Tax fees were paid in connection with the advice on tax compliance related matters.

Other Fees - Other fees were paid in connection with consultations in respect of the Company’s project controls. Management and the Audit Committee concluded that the service provided by MNP were not restricted services, and implemented monitoring safeguards to ensure independence was maintained.

### **ADDITIONAL INFORMATION**

Additional information, including directors’ and officers’ remuneration and indebtedness, principal holders of Revive’s securities, securities authorized for issuance under equity compensation plans and the Company’s corporate governance practices are contained in the Company’s Management Information Circular dated November 5, 2019 for the most recent annual meeting of shareholders held on December 18, 2019.

Additional financial information is provided in the Company’s audited Consolidated Financial Statements for the year ended June 30, 2020 and in the Company’s related Management’s Discussion and Analysis, both filed on SEDAR on October 28, 2020. A copy of the foregoing documents may be obtained by shareholders upon request from the Corporate Secretary of the Company. These documents, as well as additional information relating to Revive, are available on SEDAR at [www.sedar.com](http://www.sedar.com).

**APPENDIX A**  
**AUDIT COMMITTEE CHARTER**

## **CHARTER OF THE AUDIT COMMITTEE OF THE BOARD OF DIRECTORS**

### **I. PURPOSE**

The Audit Committee is a committee of the board of directors (the “**Board**”) of the Company. The function of the Audit Committee is to assist the Board in fulfilling its responsibilities to the shareholders of the Company, the securities regulatory authorities and stock exchanges, the investment community and others by:

- (a) reviewing the annual and interim (quarterly) financial statements, related management discussion and analysis (“**MD&A**”) and, where applicable, other financial information disclosed by the Company to any governmental body or the public, prior to its approval by the Board;
- (b) overseeing the review of interim (quarterly) financial statements and/or MD&A by the Company’s external auditor;
- (c) recommending the appointment and compensation of the Company’s external auditor, overseeing the external auditor’s qualifications and independence and providing an open avenue of communication among the external auditor, financial and senior management and the Board;
- (d) directly overseeing the work of the external auditor on the audit of annual financial statements; and
- (e) monitoring the Company’s financial reporting process and internal controls and compliance with legal and regulatory requirements related thereto.

The Audit Committee should primarily fulfill these responsibilities by carrying out the activities enumerated in Section III of this Charter. However, it is not the duty of the Audit Committee to prepare financial statements, to plan or conduct audits, to determine that the financial statements are complete and accurate and are in accordance with generally accepted accounting principles (“**GAAP**”), to conduct investigations, or to assure compliance with laws and regulations or the Company’s internal policies, procedures and controls, as these are the responsibility of management and in certain cases the external auditor.

### **II. COMPOSITION**

1. The Audit Committee shall have a minimum of three members.
2. Every Audit Committee member must be a director of the Company. The Audit Committee shall be comprised of such directors as are determined by the Board, a majority of whom shall be independent within the meaning of National Instrument 52-110 – Audit Committees (“**NI 52-110**”) of the Canadian Securities Administrators (or exempt therefrom), and free of any relationship that, in the opinion of the Board, would interfere with the exercise of his or her independent judgment as a member of the Audit Committee. Pursuant to the Business Corporations Act (Ontario) (the “**OBCA**”) the majority of the Audit Committee members must not be officers, nor employees of the Company or any of its affiliates.
3. All members of the Audit Committee must have (or should gain within a reasonable period of time after appointment) a working familiarity with basic finance and accounting practices and otherwise be financially literate within the meaning of NI 52-110 (or exempt therefrom). Audit Committee members may enhance their familiarity with finance and accounting by participating in educational programs conducted by the Company or an outside consultant.
4. The members of the Audit Committee shall be elected by the Board on an annual basis or until their successors shall be duly appointed. Audit Committee members shall hold office until the next annual meeting of shareholders subsequent to their appointment.

## SCHEDULE B

### CHARTER OF THE AUDIT COMMITTEE OF THE BOARD OF DIRECTORS

#### I. PURPOSE

The Audit Committee is a committee of the board of directors (the “**Board**”) of the Company. The function of the Audit Committee is to assist the Board in fulfilling its responsibilities to the shareholders of the Company, the securities regulatory authorities and stock exchanges, the investment community and others by:

- (a) reviewing the annual and interim (quarterly) financial statements, related management discussion and analysis (“**MD&A**”) and, where applicable, other financial information disclosed by the Company to any governmental body or the public, prior to its approval by the Board;
- (b) overseeing the review of interim (quarterly) financial statements and/or MD&A by the Company’s external auditor;
- (c) recommending the appointment and compensation of the Company’s external auditor, overseeing the external auditor’s qualifications and independence and providing an open avenue of communication among the external auditor, financial and senior management and the Board;
- (d) directly overseeing the work of the external auditor on the audit of annual financial statements; and
- (e) monitoring the Company’s financial reporting process and internal controls and compliance with legal and regulatory requirements related thereto.

The Audit Committee should primarily fulfill these responsibilities by carrying out the activities enumerated in Section III of this Charter. However, it is not the duty of the Audit Committee to prepare financial statements, to plan or conduct audits, to determine that the financial statements are complete and accurate and are in accordance with generally accepted accounting principles (“**GAAP**”), to conduct investigations, or to assure compliance with laws and regulations or the Company’s internal policies, procedures and controls, as these are the responsibility of management and in certain cases the external auditor.

#### II. COMPOSITION

1. The Audit Committee shall have a minimum of three members.
2. Every Audit Committee member must be a director of the Company. The Audit Committee shall be comprised of such directors as are determined by the Board, a majority of whom shall be independent within the meaning of National Instrument 52-110 – Audit Committees (“**NI 52-110**”) of the Canadian Securities Administrators (or exempt therefrom), and free of any relationship that, in the opinion of the Board, would interfere with the exercise of his or her independent judgment as a member of the Audit Committee. Pursuant to the Business Corporations Act (Ontario) (the “**OBCA**”) the majority of the Audit Committee members must not be officers, nor employees of the Company or any of its affiliates.
3. All members of the Audit Committee must have (or should gain within a reasonable period of time after appointment) a working familiarity with basic finance and accounting practices and otherwise be financially literate within the meaning of NI 52-110 (or exempt therefrom). Audit Committee members may enhance their familiarity with finance and accounting by participating in educational programs conducted by the Company or an outside consultant.
4. The members of the Audit Committee shall be elected by the Board on an annual basis or until their successors shall be duly appointed. Audit Committee members shall hold office until the next annual meeting of shareholders subsequent to their appointment.

5. Unless a Chair is elected by the full Board, the members of the Audit Committee may designate a Chair by majority vote of the full Audit Committee membership.
6. The Secretary of the Audit Committee will be appointed by the Chair.
7. Any member of the Audit Committee may be removed or replaced at any time by the Board and shall cease to be a member of the Audit Committee on ceasing to be a Director. The Board may fill vacancies on the Audit Committee by election from among the directors on the Board. If and whenever a vacancy shall exist on the Audit Committee, the remaining members may exercise all its powers so long as a quorum remains.

### **III. DUTIES AND RESPONSIBILITIES**

1. The Audit Committee shall review and recommend to the Board for approval:
  - (a) the Company's annual and interim financial statements, including any certification, report, opinion or review rendered by the external auditor, and review related MD&A;
  - (b) press releases of the Company that contain financial information;
  - (c) other financial information provided to any governmental body, stock exchange or the public as they see fit
  - (d) documents referencing, containing or incorporating by reference the annual audited consolidated financial statements or interim financial results (e.g., prospectuses, press releases with financial results and Annual Information Form – when applicable) prior to their release; and
  - (e) any other matter not mentioned herein but otherwise required pursuant to applicable laws, including, without limitation, NI 52-110 and the OBCA.
2. The Audit Committee, in fulfilling its mandate, will:
  - (a) satisfy itself that adequate internal controls and procedures are in place to allow the Chief Executive Officer and the Chief Financial Officer to certify financial statements and other disclosure documents as required under securities laws;
  - (b) review with management relationships with regulators, and the accuracy and timeliness of filing with regulatory authorities (when and if applicable);
  - (c) ensure that adequate procedures are in place for the review of the Company's public disclosure of financial information extracted or derived from the Company's financial statements and periodically assess the adequacy of those procedures;
  - (d) recommend to the Board the selection of the external auditor, consider the independence and effectiveness and approve the fees and other compensation to be paid to the external auditor;
  - (e) review the performance of the external auditor and approve any proposed discharge and replacement of the external auditor when circumstances warrant;
  - (f) review the annual audit plans of the internal and external auditors of the Company;
  - (g) oversee the work of the external auditor engaged for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Company;
  - (h) monitor the relationship between management and the external auditor including reviewing any management letters or other reports of the external auditor and discussing any material differences of opinion or disagreements between management and the external auditor;

- (i) periodically consult with the external auditor out of the presence of management about significant risks or exposures, internal controls and other steps that management has taken to control such risks, and the fullness and accuracy of the organization's financial statements. Particular emphasis should be given to the adequacy of internal controls to expose any payments, transactions, or procedures that might be deemed illegal or otherwise improper;
  - (j) arrange for the external auditor to be available to the Audit Committee and the full Board as needed. Ensure that the auditors communicate directly with the Audit Committee and are made accountable to the Board and the Audit Committee, as representatives of the shareholders to whom the auditors are ultimately responsible;
  - (k) ensure that the external auditors are prohibited from providing non-audit services and approve any permissible non-audit engagements of the external auditors, in accordance with applicable legislation;
  - (l) review with management and the external auditor the Company's major accounting policies, including the impact of alternative accounting policies and key management estimates and judgments that can materially affect the financial results;
  - (m) review with management their approach to controlling and securing corporate assets (including intellectual property) and information systems, the adequacy of staffing of key functions and their plans for improvements;
  - (n) review and approve the Company's hiring policies regarding partners, employees and former partners and employees of the present and former external auditor of the Company;
  - (o) review the expenses of the Chairman and President of the Company annually;
  - (p) establish procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal controls, or auditing matters and the confidential, anonymous submission by the Company's employees of concerns regarding questionable accounting or auditing matters; and
  - (q) perform such other duties as required by the Company's incorporating statute and applicable securities legislation and policies, including, without limitation, NI 52-110 and the OBCA.
3. The Audit Committee may engage independent counsel and other advisors as it determines necessary to carry out its duties, and may set and pay the compensation of such counsel and advisors. The Audit Committee may communicate directly with the Company's internal and external counsel and advisors.

#### **IV. MEETING PROCEDURES**

1. The Audit Committee shall meet at such times and places as the Audit Committee may determine, but no less than four times per year. The Audit Committee should meet within forty-five (45) days (sixty (60) days in the event the Company is a "venture issuer" (as such term is defined in National Instrument 51-102 – Continuous Disclosure Obligations)) following the end of the first three financial quarters to review and discuss the unaudited financial results for the preceding quarter and the related MD&A, and shall meet within ninety (90) days (one hundred and twenty (120) days in the event the Company is a "venture issuer") following the end of the financial year end to review and discuss the audited financial results for the preceding year and the related MD&A as well as any press release, or in both cases, by such earlier times as may be required in order to comply with applicable law or any stock exchange regulation.
2. Members of the Audit Committee shall be provided with reasonable notice of the time and place of meetings, which shall be not less than twenty-four (24) hours. The notice period may be waived by all members of the Audit Committee. Each of the Chairman of the Board, the external auditor, the Chief Executive Officer or the Chief Financial Officer shall be entitled to request that any member of the Audit Committee call a meeting.



3. The Audit Committee may ask members of management or others to attend meetings and provide pertinent information as necessary. For purposes of performing their duties, members of the Audit Committee shall have full access to all corporate information and any other information deemed appropriate by them, and shall be permitted to discuss such information and any other matters relating to the financial position of the Company with senior employees, officers and the external auditor of the Company, and others as they consider appropriate. The external auditor may, at its option, attend meetings of the Audit Committee.
4. In order to foster open communication, the Audit Committee or its Chair should meet at least annually with management and the external auditor in separate sessions to discuss any matters that the Audit Committee or each of these groups believes should be discussed privately. In addition, the Audit Committee or its Chair should meet with management quarterly in connection with the Company's interim financial statements.
5. Meetings of the Audit Committee may be conducted with members in attendance in person, by telephone or by video conference facilities.
6. Quorum for the transaction of business at any meeting of the Audit Committee shall be a majority of the number of members of the Audit Committee or such greater number as the Audit Committee shall by resolution determine.
7. A resolution in writing signed by all the members of the Audit Committee is valid as if it had been passed at a meeting of the Audit Committee.
8. The Audit Committee shall ensure that the Board is aware of matters which may significantly impact the financial condition or affairs of the Company.