



**ANNUAL INFORMATION FORM  
FOR THE FINANCIAL YEAR ENDED JUNE 30, 2018**

**April 10, 2019**

## TABLE OF CONTENTS

Cautionary Note Regarding Forward-Looking Statements .....	3
Use of Market and Industry Data.....	5
Corporate Structure.....	5
General Development of the Business.....	5
Regulatory Overview.....	9
Business of Revive .....	19
Description of Capital Structure .....	27
Dividends and Distributions .....	27
Market for Securities .....	27
Escrowed Securities.....	29
Directors and Officers .....	29
Promoter .....	31
Legal Proceedings and Regulatory Actions.....	31
Interest of Management and Others in Material Transactions .....	31
Transfer Agent and Registrar.....	31
Material Contracts .....	31
Interests of Experts .....	32
Risk Factors .....	32
Audit Committee .....	42
Additional Information .....	43
Appendix “A” Glossary.....	1
Appendix “B” Audit Committee Charter.....	1

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual information form (“**AIF**”) contains certain forward-looking information and forward-looking statements, as defined in applicable securities laws (collectively referred to herein as “**forward-looking statements**”). These statements relate to future events or to the future performance of Revive Therapeutics Ltd. (referred to herein as “**Revive**” or the “**Company**”). All statements other than statements of historical fact are forward-looking statements. Often, but not always, forward-looking statements can be identified by the use of words such as “plans”, “expects”, “is expected”, “budget”, “scheduled”, “estimates”, “continues”, “forecasts”, “projects”, “predicts”, “intends”, “anticipates” or “believes”, or variations of, or the negatives of, such words and phrases, or state that certain actions, events or results “may”, “could”, “would”, “should”, “might” or “will” be taken, occur or be achieved. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to differ materially from those anticipated in such forward-looking statements. The forward-looking statements in this AIF speak only as of the date of this AIF or as of the date specified in such statement.

The following table outlines certain significant forward-looking statements made in this AIF, the material assumptions used to develop such forward-looking statements, and material risk factors that could cause actual results to differ materially from the results anticipated in these forward-looking statements.

Forward-Looking Statements	Assumptions	Risk Factors
The Company’s (i) development of product candidates, (ii) demonstration of such product candidates’ safety and efficacy in clinical trials, and (iii) obtaining regulatory approval to commercialize these product candidates.	Financing will be available for development of new product candidates and conducting clinical studies; the actual results of the clinical trials will be favourable; development costs will not exceed Revive’s expectations; the Company will be able to retain and attract skilled staff; the Company will be able to recruit suitable patients for clinical trials; all requisite regulatory and governmental approvals to commercialize the product candidates will be received on a timely basis upon terms acceptable to Revive; applicable economic conditions are favourable to Revive.	Availability of financing in the amount and time frame needed for the development and clinical trials may not be favourable; increases in costs; the Company’s ability to retain and attract skilled staff; the Company’s ability to recruit suitable patients for clinical trials; timely and favourable regulatory and governmental compliance, acceptances, and approvals; interest rate and exchange rate fluctuations; changes in economic conditions.
The Company’s ability to obtain the substantial capital it requires to fund research and operations.	Financing will be available for Revive’s research and operations and the results thereof will be favourable; debt and equity markets, exchange and interest rates and other applicable economic conditions are favourable to Revive.	Changes in debt and equity markets; timing and availability of external financing on acceptable terms; increases in cost of research and operations; interest rate and exchange rate fluctuations; adverse changes in economic conditions.
Factors affecting pre-clinical research, clinical trials and regulatory approval process of the Company’s product candidates.	Actual costs of pre-clinical research, clinical and regulatory processes will be consistent with the Company’s current expectations; the Company will be able to retain and attract skilled staff; the Company will be able to recruit suitable patients for clinical trials; the Company will be able to complete pre-clinical research and clinical studies on a timely basis with favourable results; all applicable regulatory and governmental approvals for product candidates will be received on a timely basis with terms acceptable to Revive; debt and equity markets, exchange and interest	Revive’s product candidates may require time-consuming and costly pre-clinical and clinical studies and testing and regulatory approvals before commercialization; the Company’s ability to retain and attract skilled staff; the Company’s ability to recruit suitable patients for clinical trials; adverse changes in regulatory and governmental processes; interest rate and exchange rate fluctuations; changes in economic and political conditions; the Company will not be adversely affected by market

Forward-Looking Statements	Assumptions	Risk Factors
	rates, and other applicable economic and political conditions are favourable to Revive; there will be a ready market for the product candidates.	competition.
The Company's ability to commercialize on its own or find and enter into agreements with potential partners to bring viable product candidates to commercialization.	Revive will be able to commercialize on its own or to find a suitable partner and enter into agreements to bring product candidates to market within a reasonable time frame and on favourable terms; the costs of commercializing on its own or entering into a partnership will be consistent with Revive's expectations; partners will provide necessary financing and expertise to bring product candidates to market successfully and profitably.	Revive will not be able to commercialize on its own or find a partner and/or enter into agreements within a reasonable time frame; if the Company enters into agreements, these agreements may not be on favourable terms to Revive; costs of entering into agreements may be excessive; potential partners will not have the necessary financing or expertise to bring product candidates to market successfully or profitably.
The Company's ability to obtain and protect the Company's intellectual property rights and not infringe on the intellectual property rights of others.	Patents and other intellectual property rights will be obtained for viable product candidates; patents and other intellectual property rights obtained will not infringe on others.	Revive will not be able to obtain appropriate patents and other intellectual property rights for viable product candidates; patents and other intellectual property rights obtained will be contested by third parties; no proof that acquiring a patent will make the product more competitive.
The Company's ability to source markets which have demand for its products and successfully supply those markets in order to generate sales.	The anticipated markets for the Company's potential products and technologies will continue to exist and expand; the Company's products will be commercially viable and it will successfully compete with other research teams who are also examining potential products and therapeutics with regards to cannabinoids, gout, cystinuria, Wilson's disease, rare diseases, pain, inflammatory skin diseases, liver diseases, inflammation, autoimmune, and central nervous system disorders.	The anticipated market for the Company's potential products and technologies will not continue to exist and expand for a variety of reasons, including competition from other products and the degree of commercial viability of the potential product.
Future actions with respect to and potential impacts of pending claims.	Revive will be able to settle or otherwise obtain disposition of claims against it on favourable terms.	Revive may will not be able to settle pending claims on favourable terms; claims may be adjudicated in a manner that is not favourable to Revive.

Inherent in forward-looking statements are risks, uncertainties and other factors beyond Revive's ability to predict or control. Please also make reference to those risk factors referenced in the "Risk Factors" section below. Readers are cautioned that the above chart does not contain an exhaustive list of the factors or assumptions that may affect the forward-looking statements, and that the assumptions underlying such statements may prove to be incorrect.

Actual results and developments are likely to differ, and may differ materially, from those expressed or implied by the forward-looking statements contained in this AIF.

Forward looking statements involve known and unknown risks, uncertainties and other factors that may cause Revive's actual results, performance or achievements to be materially different from any of its future results, performance or achievements expressed or implied by forward looking statements. All forward looking statements herein are qualified by this cautionary statement. Accordingly, readers should not place undue reliance on forward looking statements. The Company undertakes no obligation to update publicly or otherwise revise any forward looking statements whether as a result of new information or future events or otherwise, except as may be required by law. If the Company does update one or more forward looking statements, no inference should be drawn that it will make additional updates with respect to those or other forward looking statements, unless required by law.

## USE OF MARKET AND INDUSTRY DATA

This AIF includes market and industry data that has been obtained from third party sources, including industry publications, as well as industry data prepared by the Company's management on the basis of its knowledge of and experience in the industry in which the Company operates (including management's estimates and assumptions relating to the industry based on that knowledge). Management's knowledge of the industry has been developed through its experience and lengthy participation in the industry. Management 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 believed to be reliable, the Company's management 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.

## CORPORATE STRUCTURE

### Name, Address and Incorporation

Revive Therapeutics Inc. ("**Old Revive**") was incorporated on August 7, 2012, under the *Business Corporations Act* (Ontario) (the "**OBCA**"). On December 30, 2013, Old Revive completed a reverse take-over ("**RTO**") of Mercury Capital II Limited ("**Mercury**").

Pursuant to the RTO, Old Revive, Mercury, and a subsidiary of Mercury completed a triangular amalgamation under the OBCA pursuant to which shares of Old Revive were exchanged for shares of Mercury on the basis of one (1) Mercury share for each one (1) Old Revive share, all of the outstanding shares of Old Revive were acquired by Mercury Capital III Limited ("**Mercury AcquisitionCo**"), Old Revive and Mercury AcquisitionCo were amalgamated, and the resulting company, named Revive Therapeutics Inc. ("**Revive Inc.**"), continued as a wholly-owned subsidiary of Mercury (the "**Amalgamation**"). Upon completion of the Amalgamation, Mercury's articles of incorporation were amended to change its name to "Revive Therapeutics Ltd."

Mercury was incorporated under the OBCA on March 27, 2012. Prior to the completion of the RTO, Mercury was classified as a capital pool company under the policies of the TSX Venture Exchange ("**TSX-V**"), and accordingly, had no commercial operations, and no significant assets other than cash. Completion of the RTO constituted a qualifying transaction as defined by the TSX-V for Mercury.

The Company's head and registered office is located at 5 Director Court, Suite 105, Vaughan, Ontario, L4L 4S5.

### Intercorporate Relationships

The Company owns 100% of the issued and outstanding shares of Revive Inc., which is its only subsidiary.

## GENERAL DEVELOPMENT OF THE BUSINESS

The Company is focused on the research, development and commercialization of novel cannabinoid-based products. The business of the Company was previously focused on the advancement of repurposing the drug buccillamine for

the treatment of gout (pain from flares) and cystinuria (kidney stones). As at June 30, 2018, the Company had changed its primary business to focus on the research, development and commercialization of novel cannabinoid-based products.

### **Three Year History**

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

The Company's 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"). 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 United States Food and Drug Administration ("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 novel cannabinoid-based products. 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-004 program as it focuses its attention on the research, development and commercialization of novel cannabinoid-based products. See "*Regulatory Overview - U.S. Government Regulation*" for a description of the FDA's Orphan Drug Designation and Clinical Trials process.

The Company is presently in the process of winding down the aspect of its business related to the development of the drug bucillamine.

#### *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 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 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 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-a) 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 November 25, 2015, the Company announced that it had been listed for trading on the OTCQB® Market exchange in the United States under the symbol “RVVTF”.

On June 17, 2016, the Company completed a rights offering for gross proceeds of \$844,693.

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.

*Business Developments Subsequent to the Financial Year Ended June 30, 2018*

Since its June 30, 2018 financial year end, the Company has continued its focus on the research, development and commercialization of novel cannabinoid-based products.

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. In November 2018, the FDA granted orphan drug designation for CBD in the prevention of IRI resulting from 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.

- (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.

### **Significant Acquisitions**

The Company did not complete any acquisitions during the financial year ended June 30, 2018, 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 for Cannabis**

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.

### ***U.S. Government Regulation***

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 preclinical studies, animal studies, and formulation studies in compliance with the FDA’s Good Laboratory Practice, regulations;
- submission to the FDA of an IND application to support human clinical testing in the United States;
- approval by an IRB at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with federal regulations and with Good Clinical Practices (“**GCP**”), and regulations to establish the safety and efficacy of the investigational product candidate for each target indication;
- submission of a New Drug Application (“**FDA-NDA**”) to the FDA;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the investigational product candidate is produced to assess compliance with the FDA’s Current Good Manufacturing Practice (“**cGMP**”) regulations, and to assure that the facilities, methods, and controls are adequate; and
- FDA review and approval of the FDA-NDA.

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

## 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 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.

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<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)

## 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 1 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.

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

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<sup>3</sup> <https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/significantamendmentstothefdact/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>

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.

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

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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>



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.

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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>

## BUSINESS OF REVIVE

### Overview

The Company is a company focused on the research, development, and commercialization of novel cannabinoid-based products. Revive is commercializing novel delivery and patent-protected cannabis-based products in the multi-billion dollar cannabis and health and wellness market. The Company's novel cannabinoid 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 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**

### ***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.

Due to the mounting data from pre-clinical and clinical research the therapeutic effects of cannabis and the safety benefits of cannabinoids has led to significant interest from small-to-medium sized specialty pharmaceutical companies. Currently there are a number of cannabinoid products approved in US or EU: Sativex<sup>TM</sup> (GW Pharma), Marinol<sup>TM</sup> (AbbVie), Cesamet<sup>TM</sup> (Meda), and dronabinol, a synthetic THC (Insys). There are many companies supplying synthetic cannabinoids, cannabis extracts, and herbal cannabis to researchers for pre-clinical and clinical investigation for a number of diseases including cancer, diabetes, neuromuscular disorders, treatment of nausea, loss of appetite, pain relief, and muscle relaxation for cancer, HIV, multiple sclerosis, and arthritis patients. The cannabinoid-based medical use and pharmaceutical market is expected to grow significantly due to the potential benefits these products may provide over existing therapies.

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*".

### ***Drug delivery technology***

The Company is focused on commercializing novel delivery technologies to effectively deliver cannabinoids through the skin and/or directly into the affected area of the skin, otherwise known as topical delivery and also via the mouth, otherwise known as buccal delivery.

The potential advantages of these delivery mechanisms of cannabinoids are:

- better bioavailability, while bypassing the first-pass hepatic metabolism;
- faster and/or reliable onset of action;
- precise dosing that is consistent, accurate and repeatable;
- avoid irritation in the lungs, throat and stomach;
- ease of use for improved consumer and patient adherence and compliance;
- higher acceptance for those who find smoking or swallowing difficult; and
- potential for improved blood circulation to brain, cognitive function, and hygiene.

### **Proposed topical drug delivery technology**

The Company's topical cannabinoid delivery technology will initially deliver CBD in combination with chitosan and tannins in a controlled or sustained release fashion, systemically or locally, through the skin. The chitosan has

blood-clotting and antimicrobial properties and tannins have antibacterial, antifungal, antioxidant and wound healing properties. The combination of cannabinoids, tannin, and chitosan has the potential to become a unique delivery technology to serve broad market opportunities for the health and wellness, medical and pharmaceutical cannabinoid markets. The Company's cannabinoid 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*".

#### Proposed buccal cannabinoid delivery technology

The Company's buccal delivery technology, based on microencapsulation, will initially deliver either THC or CBD alone or as a combination of THC and CBD for the recreational and medical cannabis and health and wellness market. The initial format will be in the form of a chewing gum. In its natural form, cannabinoids are lipophilic, not water-soluble, and tend to stick to the chewing gum matrix, therefore diminishing effective release into the bloodstream. Microencapsulation renders cannabinoids soluble and dramatically increases the bioavailability of CBD, while largely bypassing the first pass hepatic metabolism. The Company is also investigating rapid dissolving applications to deliver cannabinoids via the buccal route.

The Company's buccal delivery technology involving chewing gum is from Axim. The Company, through Revive 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 intends to market this product under the brand name RELICANN™. The Company is in the process of seeking regulatory approval for RELICANN™. Under the terms of the Axim Agreement, the Company has annual minimum purchase amount obligations, which increase each year for the term of the agreement.

#### 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.

#### *Potential Target Markets*

The Company is expanding its product pipeline with novel cannabinoid-centric treatments for liver diseases pain, inflammation and skin disorders.

#### Liver diseases

Liver disease is described by irregular functioning of the liver, causing disorders like hepatitis, fatty liver, and cirrhosis. There are over 100 described diseases of the liver<sup>13</sup> affecting at least 30 million people alone in the U.S.<sup>14</sup> A number of factors are driving the liver disease treatment market, which include rapidly changing lifestyle patterns such as increasing alcohol consumption, unhealthy diets, and increasing prevalence of liver diseases. Liver diseases can result from injury to the liver caused by hepatitis C virus, hepatitis B virus, obesity, chronic excessive alcohol use, or autoimmune diseases. Major drug categories used in the treatment of liver diseases includes anti-rejection drugs, vaccines, immunosuppressant, chemotherapy drugs, and antiviral drugs. According to Allied Market

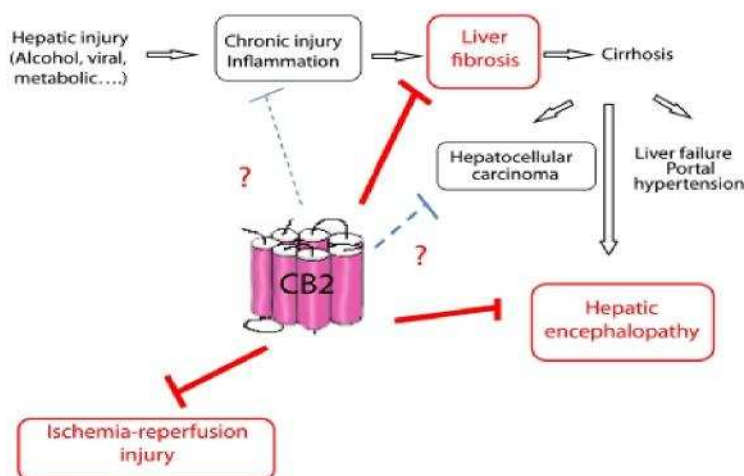
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<sup>13</sup> <https://www.liver.ca/patients-caregivers/liver-diseases/>

<sup>14</sup> <https://liverfoundation.org/for-patients/about-alf/>

Research, titled, “World Liver Disease Treatment Market - Opportunities and Forecast, 2014 - 2022”, the global market for liver disease treatment is projected to reach \$19.5 billion by 2022.

Recent data have unraveled a key role of CB2 receptors during chronic and acute liver injury, including fibrogenesis associated to chronic liver diseases, ischemia-reperfusion (I/R)-induced liver injury, and hepatic encephalopathy associated to acute liver failure. It has recently been shown that hepatic CB2 receptors are highly upregulated in several pathological conditions. Overall, the figure below indicates CB2 as a target for following liver indications: fibrosis, I/R-induced injury, and hepatic encephalopathy.



Research has also indicated that the non-psychoactive cannabinoid, CBD, protects against hepatic ischemia/reperfusion injury by attenuating inflammatory signaling and response, oxidative/nitrative stress, and cell death. CBD significantly reduced the extent of liver inflammation, oxidative/nitrative stress, and cell death and also attenuated the bacterial endotoxin-triggered. CBD may represent a novel, protective strategy against I/R injury by attenuating key inflammatory pathways and oxidative/nitrative tissue injury, independent of classical CB1/2 receptors. These results emphasize that CBD represents a potential therapeutic option to protect the liver against hypoxia-reoxygenation injury. The available data suggest that CB2 agonists may offer novel perspectives in prevention of hepatic I/R injury. CB2 receptor mediates protection against hepatic ischemia/reperfusion injury. Potentially targeting the CB2 receptor may represent a novel protective strategy against I/R injury.

Based on research, CB2 agonists have demonstrated potential for alcoholic steatohepatitis.  $\beta$ -caryophyllene (“BCP”), a CB2 receptor agonist, also known as the “dietary cannabinoid / phytocannabinoid,” has been demonstrated to protect against alcoholic steatohepatitis by attenuating inflammation and metabolic dysregulation in mice.<sup>15</sup> Given the safety of BCP in humans, this food additive has a high translational potential in treating or preventing hepatic injury associated with oxidative stress, inflammation, and steatosis. Given the excellent safety profile of BCP in humans, it has tremendous therapeutic potential in a multitude of diseases associated with inflammation and oxidative stress, even those outside of the liver indication. Chronic treatment with BCP attenuated the chronic and binge alcohol-induced liver injury and inflammation by attenuating the pro-inflammatory phenotypic M1 switch of Kupffer cells and by decreasing the expression of vascular adhesion molecules ICAM-1, E-Selectin, and P-Selectin, as well as the neutrophil infiltration. The protective effects of BCP against alcohol-induced liver injury were attenuated in CB2 knockout mice, indicating that the beneficial effects of this natural product in liver injury involve CB2 receptor activation. In a separate study, BCP was used to investigate the role of the CB2 receptors in mediating alcohol intake and ethanol-induced conditioned place preference and sensitivity in mice. The results indicated that BCP dose-dependently reduced alcohol consumption and preference. Overall, the CB2 receptor system appears to be involved in alcohol dependence and sensitivity and may represent a potential pharmacological target for the treatment of alcoholism. These data identify CB2 agonists as potential therapeutic agents for the management of alcoholic liver disease and identify the CB2 receptor as a potential therapeutic target. In summary, BCP represents untapped compound potential from a therapeutic perspective, has demonstrated safety profiles in humans, and there is minimal competition to date in terms of investigation and

<sup>15</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5758392/>

commercialization. There is an opportunity to formulate this, synthesize analogues, and investigate clinical efficacy. This compound is of particular interest as it is a CB2 agonist, not psychoactive, and is referred to in the literature as a “dietary cannabinoid.” The chemical structure is significantly different compared to the cannabinoid structure class as whole.

Research has also suggested that cannabinoids have shown potential for non-alcoholic fatty liver disease (“NAFLD”). A study in 2015 investigating two non-psychoactive cannabinoids,  $\Delta$ 9-Tetrahydrocannabinol (“THCV”) and CBD, as potential therapeutics for NAFLD. The result of this study, from in vitro and in vivo models, demonstrated that both THCV and CBD directly reduced accumulated lipid levels in vitro in a hepatosteatosis model and adipocytes.<sup>16</sup>

Based on previous research CB2 agonists have shown potential for liver injury and regeneration. A study in the literature that has previously investigated the impact of CB2 receptors on the regenerative process associated with liver injury using JWH133, a CB2 synthetic CB2 receptor agonist.<sup>17</sup> These results suggested that CB2 agonists display potent hepatoprotective properties, in addition to their antifibrogenic effects. CB2 receptors reduce liver injury and promote liver regeneration following acute insult, via distinct paracrine mechanisms involving hepatic myofibroblasts.

Research also suggests that cannabis’ anti-inflammatory and protective properties help in the treatment of hepatitis. One study found that cannabinoids’ anti-inflammatory properties effectively reduced inflammation of a damaged liver and researchers therefore suggested that cannabis could be developed as a potential drug for hepatitis.<sup>18</sup> Another study found that cannabinoids appeared to have immunosuppressive and profibrogenic effects in patients with chronic hepatitis C.<sup>19</sup>

The Company is in the research and development phase of next generation or novel uses of cannabinoids for the treatment of a variety of liver diseases.

#### Research and Development Programs in Liver Diseases

Liver disease is a major cause of morbidity and mortality and the prognosis is often poor. In many liver diseases (such as viral hepatitis, AIH and alcoholic liver disease), activated T lymphocytes and macrophages appear to play an important role in liver damage. AIH is an inflammatory liver disease characterized by the presence of high transaminases, circulating autoantibodies, hypergammaglobulinemia, histological evidence of hepatitis, and responsiveness to immunosuppressive treatment. The ten year survival rate in untreated patients is approximately 10%. The two known types of AIH (type I and type II) are treated with corticosteroids such as prednisone as well as other immunosuppressive drugs such as azathioprine, mycophenolate mofetil, cyclosporine or tacrolimus. Patients who progress to end stage liver disease and/or cirrhosis may also need a liver transplant. Therefore, alternative treatment options are needed. Therapeutic approaches that either inhibit immune-mediated mechanisms or directly inhibit liver cell damage show promise. These studies have addressed the mechanism underlying the use of CAM therapy in ameliorating hepatitis and liver damage. While extensive studies have been performed to elucidate the mechanism of viral hepatitis, there is paucity of information on the pathogenesis of AIH and a dire need for the development of CAM therapy to treat such patients.

The Company is investigating the process of conducting further research and development work with CBD in relevant AIH animal models. The overall objective is to support CBD for the potential treatment of AIH that the Company may potentially advance to further pre-clinical and human clinical research and partner with companies with a focus on liver diseases and specialty cannabinoid treatments. The Company was granted orphan drug designation for CBD in the treatment of AIH by the FDA.

Pursuant to the SCRF License Agreement, the Company, through Revive 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

<sup>16</sup> <https://www.ncbi.nlm.nih.gov/pubmed/25595882>

<sup>17</sup> <https://aasldpubs.onlinelibrary.wiley.com/doi/pdf/10.1002/hep.23779>

<sup>18</sup> <https://www.ncbi.nlm.nih.gov/pubmed/14645663>

<sup>19</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4425004/>

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.

The Company, through Revive Inc., has also entered into a research collaboration with SanyalBio focused on advancing cannabinoids for the potential treatment of liver diseases. The collaboration will initially focus on the use of CBD on a novel AIH model based on SanyalBio's DIAMOND™ model designed and developed by SanyalBio specifically for Revive. 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.

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. Quickly restoring blood supply of ischemic organs 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 organ functions in the case of acute injuries. 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. The Company 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. The Company submitted an application to the FDA seeking orphan drug designation of CBD for the treatment of hepatic IRI during liver transplantation. The application resulted in the FDA granting orphan drug designation for CBD in the prevention of IRI resulting from solid organ transplantation.

### Pain

According to a research report conducted by Research Report Insights, the global market for neuropathic pain valued at over US \$5 Billion and is estimated to grow to US \$8.3 Billion by 2024.

The Company's proposed topical cannabinoid products would be designed to provide safe, effective relief from the pain of peripheral neuropathies. Peripheral neuropathies, or also known as neuropathic pain, are medical conditions caused by damage to the nerves in the peripheral nervous system. The peripheral nervous system includes nerves that run from the brain and spinal cord to the rest of the body. These conditions are caused from injured peripheral nerves, following herpes zoster, shingles, diabetes, chemotherapy, HIV, and other diseases. Peripheral neuropathies can also be caused by trauma or may result from surgical procedures. Additional neuropathic pain indications include lower back pain, cancer-related neuropathic pain, complex regional pain syndrome, and postoperative neuropathic pain.

Peripheral neuropathic pain generally is treated with tricyclic antidepressants, anticonvulsants such as duloxetine, depakote, pregabalin, gabapentin and topiramate, and serotonin/norepinephrine reuptake inhibitors, or SNRIs. Although tricyclic antidepressants, anticonvulsants, and SNRIs often show efficacy in treating neuropathic pain, they also have many drawbacks, including poor tolerability with side effects in most patients.

The Company's proposed topical cannabinoid products may have the potential to treat a number of neuropathic pain indications more safely and effectively than that of traditional cannabinoid products and current natural health and drug treatments for these indications. See "*Drug delivery technology.*"

The Company's proposed topical cannabinoid products will also expand use in additional pain disorders in the future.



## Inflammatory skin disorders

Inflammatory skin disorders are the result of immune system reactions that involve the skin. Psoriasis is a chronic inflammatory skin disease that affects approximately 7.5 million people in the US.<sup>20</sup> The disease is characterized by an errant immune-system response that drives inflammation and thickening of the skin caused by rapid turnover of skin cells. Psoriasis and other inflammatory skin diseases such as atopic dermatitis can cause tremendous discomfort. The healthcare market has seen an increase in the introduction of systemic therapies, including biologics, to treat patients with moderate-to-severe psoriasis and atopic dermatitis. For the majority of affected patients with less severe disease burden, topical corticosteroids are the predominant therapies prescribed. None of the currently approved therapies are without side effects, and none are well-suited for chronic use. Currently, in the United States, psoriasis is a \$5 billion market, of which 90% are from drugs targeting moderate to severe psoriasis patients where the skin manifestation affects more than 3% of the body.<sup>21</sup>

The Company's proposed topical cannabinoid products may have the potential to treat a number of inflammatory skin disorders more safely and effectively than that of traditional cannabinoid products and current natural health and drug treatments for these indications. The Company's proposed topical cannabinoid products may also be explored for additional inflammatory skin disorders and wound healing indications in the future.

### **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, 2018, the estimated cost to complete the product candidate and the Company's commercialization rights with respect to the product candidate.

<b>Program</b>	<b>Status</b>	<b>Next Milestone</b>	<b>Amount Spent during Financial Year ended June 30, 2018</b>	<b>Estimated Cost to Complete (2019)</b>	<b>Commercialization Rights</b>
Cannabinoids for Liver Diseases	Signed SCRF License Agreement.  Initiated research study with SanyalBio.	Initiate research in various research models of liver diseases  Complete research study of CBD in AIH animal model	Approximately \$29,000 was spent during the year ended June 30, 2018	\$50,000	Worldwide
Cannabinoid Delivery Technology	Signed WARF License Agreement.  Completed the University of Wisconsin-Madison Research Program.	Conduct research and development of formulations  Conduct research studies in various disease models	Approximately \$179,000 was spent during the year ended June 30, 2018	\$100,000	Worldwide

<sup>20</sup> <https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers>

<sup>21</sup> <https://decisionresourcesgroup.com/drg-blog/biologics-continue-flare-psoriasis-market-indicating-opportunities-larger-dermatology-space/>

Program	Status	Next Milestone	Amount Spent during Financial Year ended June 30, 2018	Estimated Cost to Complete (2019)	Commercialization Rights
Cannabinoid Products	Signed Axim Agreement with Axim for CBD-based chewing gum.	Regulatory approval to market in Canada (as of the date of this AIF, the Company has submitted the application for regulatory approval to Health Canada)  Commercialization in Canada	Approximately \$35,000 was spent during the year ended June 30, 2018	\$75,000	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 has 3 employees. The Company also retains, from time to time, contractors and consultants to perform specialized services. See “*Risk Factors*”.

## Reorganizations

Since July 1, 2015, 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 72,411,282 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

The Company has not paid any dividends on its common shares since its incorporation. The Company is not in production and has no present intention of paying dividends on its common shares, as it anticipates that all available funds will be invested to finance the development of its business.

## MARKET FOR SECURITIES

### Trading Price and Volume

The Company’s common shares currently trade on the TSX-V under the symbol “RVV”, on the OTCQB<sup>®</sup> under the symbol “RVVTF” and the Frankfurt Stock Exchange in Germany under the symbol “31R”. The following table sets forth the volume of trading and price ranges of the common shares on the TSX-V for each month during the period from July 2017, to June 2018:

TRADING PRICE AND VOLUME			
Period	High (\$)	Low (\$)	Volume
June 2018	0.295	0.15	7,847,300
May 2018	0.245	0.185	1,994,960

**TRADING PRICE AND VOLUME**

Period	High (\$)	Low (\$)	Volume
April 2018	0.23	0.175	2,926,650
March 2018	0.27	0.21	3,135,220
February 2018	0.33	0.21	5,094,370
January 2018	0.51	0.31	20,530,880
December 2017	0.475	0.24	27,538,640
November 2017	0.375	0.15	25,262,140
October 2017	0.215	0.16	3,912,640
September 2017	0.2	0.13	3,317,320
August 2017	0.2	0.15	2,462,070
July 2017	0.205	0.18	2,259,360

**Prior Sales**

Outstanding securities issued by the Company that are not traded or listed on a marketplace consist of common share purchase warrants and stock options. Both can be exercised to acquire common shares during a specified period of time by paying the stated exercise price to the Company.

**(a) Warrants**

As at June 30, 2018, the Company had no warrants issued and outstanding.

As at the date of this AIF, the Company had 14,010,000 warrants issued and outstanding. Each warrant entitles the holder to acquire one common share at a price of \$0.15 per common share. See “*Business Developments Subsequent to the Financial Year Ended June 30, 2018*”.

**(b) Stock Options**

The Company has an incentive stock option plan for the purchase of common shares for its directors, officers, employees, management company employee or consultants of the Company or a subsidiary of the Company. The aggregate number of common shares reserved for issuance under the stock option plan is 10% of the issued and outstanding shares at the time of grant.

As at June 30, 2018, the Company had 3,470,375 options issued and outstanding.

As at the date of this AIF, the Company had 4,045,375 options issued and outstanding, as summarized in the table below:

Number of Options	Issue/Exercise Price per Option	Date of Issue
40,375	\$0.30	09-Jul-13
590,000	\$0.66	31-Jan-14
925,000	\$0.60	11-Feb-15
965,000	\$0.28	10-Apr-17

250,000	\$0.20	01-Nov-17
350,000	\$0.325	29-Nov-17
350,000	\$0.205	08-Jun-18
75,000	\$0.205	21-Aug-18
500,000	\$0.19	11-Oct-18

### ESCROWED SECURITIES

To the knowledge of the Company, there are no common shares of the Company held in escrow or subject to a contractual restriction on transfer as at the date of this AIF.

### DIRECTORS AND OFFICERS

#### Name, Occupation and Security Holding

The following table sets forth, for each of the directors and executive officers of the Company as at the date of this AIF, the person's name, municipality of residence, position with the Company, principal occupation during the preceding five years and, if a director, the year in which the person became a director. Each of the directors of the Company has been appointed to serve until the next annual meeting of shareholders of the Company.

<u>Name and Municipality of Residence</u>	<u>Principal Occupation during the last five years</u>	<u>Director Since</u>	<u>Position with the Company</u>	<u>Number of Common Shares Beneficially Owned or Controlled<sup>(1)</sup></u>
Fabio Chianelli <i>Woodbridge, Ontario Canada</i>	President of Revive July 2016 to present); CEO of Revive (Jan. 2014 to June.	Jan. 2014	President and Director	6,870,600
Craig Leon <sup>(2)</sup> <i>Toronto, Ontario Canada</i>	CEO of Revive (July 2016 to present)	Jan. 2014	Director	1,380,000
Carlo Sansalone <sup>(2)</sup> <i>Vaughan, Ontario Canada</i>	President of Sanscon Construction Ltd. (Jan. 1999 to present).	Jan. 2014	Director	1,951,666
William Jackson <sup>(2)</sup> <i>Hamilton, Ontario Canada</i>	CEO of Atwill Medical Solutions (Jul. 2011 to present); co-founder and various senior management roles, including CFO, COO, Chief Business Officer, and director at Covalon Technologies Ltd. (Dec. 2004 to Jan. 2013); Director of Titan Medical Inc. (Apr. 2008 to Jun. 2010).	Jan. 2014	Director	Nil
Carmelo Marrelli <i>Woodbridge, Ontario</i>	President of Marrelli Support Services Inc. (Feb. 2009 to present); Partner at Marrelli & Drake Corporate Services (Jan. 2001 to Jan. 2009)	N/A	CFO	Nil
Beverly J. Incedon <i>George Town, Cayman</i>	VP, Research & Development of Ironshore Pharmaceuticals and Development (Jan. 2014 to present);	N/A	Vice President, Research &	Nil

Islands

President of Concept 2 Clinic Inc. (Jan. 2010 to Jan. 2014); VP, Research & Development of Pacgen Biopharmaceutics Corporation (Apr. 2009 to Jan. 2010); Director of Research & Development of Eli Lilly Canada, Inc. (Apr. 2006 to Apr. 2009).

Development

Notes:

- (1) The information as to voting securities beneficially owned, controlled or directed, not being within the knowledge of the Company, has been furnished by the respective nominees individually.
- (2) Member of the Audit Committee.

As at the date of this AIF, the current officers and directors of the Company as a group, directly or indirectly, beneficially own or exercise control or direction over 10,202,266 common shares, representing approximately 14.09% of the Company's issued and outstanding common shares.

### **Cease Trade Orders, Bankruptcies, Penalties or Sanctions**

No director or executive officer of the Company is, as at the date of this AIF, or has been, was within ten years before the date of this AIF, a director or chief executive officer or chief financial officer of any company that:

- (i) was the subject of an order (as defined in Form 51-102F2 – *Annual Information Form* of NI 51-102) that was issued while the director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer; or
- (ii) was subject to an order that was issued after such individual ceased to be a director, chief executive officer, or chief financial officer, and which resulted from an event that occurred while that individual was acting in the capacity as a director, chief executive officer, or chief financial officer.

No director, executive officer, or shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company, or personal holding company of any such individual

- (i) is at the date hereof, or has been within the ten years before the date of this AIF, a director or executive officer of any company that while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets; or
- (ii) has, within the ten years before the date of this AIF, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of the director, executive officer or shareholder.

No director, executive officer, or shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company, or personal holding company of any such individual has been subject to

- (i) any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or
- (ii) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

## **Conflicts of Interest**

Other than as disclosed herein, 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.

## **PROMOTER**

No person or company, within the two most recently completed financial years or during the current financial year, has been a promoter of the Company.

## **LEGAL PROCEEDINGS AND REGULATORY ACTIONS**

Except as set forth 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 dispute is in arbitration.

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

No director, executive officer or insider of the Company, or any associate or affiliate of any of them, has or has had any material interest, direct or indirect, in any transaction within the three most recently completed financial years or during the current financial year of the Company that has materially affected or is reasonably expected to materially affect the Company.

## **TRANSFER AGENT AND REGISTRAR**

The Company's transfer agent and registrar for its common shares is Computershare Investor Services Inc., 510 Burrard Street, 3rd Floor, Vancouver, British Columbia, V6C 3B9.

## **MATERIAL CONTRACTS**

The Company has not entered into any material contract, other than those entered into in the normal course of business, within the most recently completed financial year, or before the most recently completed financial year that is still in effect.

## **INTERESTS OF EXPERTS**

MNP LLP, Chartered Accountants are the auditors of the Company and have confirmed that they are independent with respect to the Company within the meaning of the Chartered Professional Accountants of Ontario Rules of Professional Conduct.

## **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.

### ***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.

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

The Company's articles permit the issuance of an unlimited number of common shares. The Company may issue additional common shares in the future, which may dilute a shareholder's holdings in the Company.

#### ***Issuance of Debt***

From time to time, the Company may enter into transactions to acquire assets or the shares of other corporations. These transactions may be financed partially or wholly with debt, which may increase the Company's debt levels above industry standards. The level of the Company's indebtedness from time to time could impair the Company's ability to obtain additional financing in the future on a timely basis to take advantage of business opportunities that may arise.

#### ***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.

#### ***Delays in projected development goals***

The Company sets goals for, and makes public statements regarding, the expected timing of the accomplishment of objectives material to its success, the commencement and completion of clinical trials and the expected costs to develop its product candidates. The actual timing and costs of these events can vary dramatically due to factors within and beyond the Company's control, such as delays or failures in our clinical trials, issues related to the manufacturing of drug supply, uncertainties inherent in the regulatory approval process, market conditions and interest by partners in the Company's product candidates among other things. The Company may not make regulatory submissions or receive regulatory approvals as planned; its clinical trials may not be completed; or it may not secure partnerships for any of our product candidates. Any failure to achieve one or more of these milestones as planned would have a material adverse effect on our 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.

### ***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.

### ***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*".

### ***Litigation to Protect the Company's Intellectual Property***

The Company's future success and competitive position depends in part upon its ability to maintain its intellectual property portfolio. There can be no assurance that any patents will be issued on any existing or future patent applications. Even if such patents are issued, there can be no assurance that any patents issued or licensed to the Company will not be challenged. The Company's ability to establish and maintain a competitive position may be achieved in part by prosecuting claims against others who it believes to be infringing its rights. In addition, enforcement of the Company's patents in foreign jurisdictions will depend on the legal procedures in those jurisdictions. Even if such claims are found to be invalid, the Company's involvement in intellectual property litigation could have a material adverse effect on its ability to distribute any products that are the subject of such litigation. In addition, the Company's involvement in intellectual property litigation could result in significant expense, which could materially adversely affect the use responsibilities, whether or not such litigation is resolved in the Company's favour.

### ***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 licence 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.

### ***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.

### ***Agricultural Operations Risk***

The Company is dependent on the growth and production of industrial cannabis and hemp, an agricultural product. As such, the risks inherent in engaging in agricultural businesses apply to the Company. Potential risks include the risk that crops may become diseased or victim to insects or other pests and contamination, or subject to extreme weather conditions such as excess rainfall, freezing temperature, or drought, all of which could result in low crop yields, decreased availability of industrial hemp and cannabis, and higher acquisition prices. Although the Company sources or plans to source its cannabis or CBD-hemp oil from hemp grown in permitted environments, there can be no guarantee that an agricultural event will not adversely affect the Company's business and operating results.

### ***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.

### ***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.

### ***Changes in laws and regulations***

The Company endeavours to comply with all relevant laws, regulations and guidelines. To the Company's knowledge, it is in compliance with all such laws, regulations, and guidelines as described elsewhere in this prospectus.

On June 30, 2016, the Government of Canada established the Task Force on Cannabis Legalization and Regulation to seek input on the design of a new system to legalize, strictly regulate, and restrict access to adult-use recreational cannabis. On December 13, 2016, the Task Force completed its review and published a report outlining its recommendations.

On April 13, 2017, the federal government of Canada introduced the *Cannabis Act* (Canada). On June 20, 2018 the Senate approved the *Cannabis Act* (Canada) and the *Cannabis Act* (Canada) received Royal Assent on June 21, 2018. The *Cannabis Act* (Canada) came into effect on October 17, 2018. The *Cannabis Act* (Canada) creates a strict legal framework for controlling the production, distribution, sale and possession of recreational cannabis in Canada. The *Cannabis Act* (Canada) lifts the ban on the recreational use of cannabis in Canada dating back to 1923. The impact of any such new legislative system on the medical cannabis industry and the Company's business plan and operations is uncertain.

In addition, with the recent coming into effect of the *Cannabis Act* (Canada), there is no guarantee that provincial legislation regulating the distribution and sale of cannabis for recreational purposes will be enacted according to the terms announced by such provinces, or at all, or that any such legislation, if enacted, will create the opportunities for growth anticipated by the Company. For example, the Provinces of Ontario (Canada's most populous province), Québec, and New Brunswick have announced sales and distribution models that would create government-controlled monopolies over the legal retail and distribution of cannabis for recreational purposes in such provinces, which could limit the Company's opportunities in those provinces. On August 13, 2018, the Ontario government announced that it will consult with various government agencies, community groups, and industry stakeholders in order to structure a private retail model in Ontario for cannabis, which came into effect in April 2019.

### ***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 you 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 factors 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 it 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.

***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.

***Maintaining and Promoting the Company's Brands***

Revive believes that maintaining and promoting the Company's brands is critical to expanding the Company's customer base. Maintaining and promoting the Company's brands will depend largely on its ability to continue to provide quality, reliable, and innovative products, which the Company's may not do successfully. Revive may introduce new products and technologies that the Company's customers do not like, which may negatively affect the Company's brand and reputation. Maintaining and enhancing the Company's brands may require substantial investments, and these investments may not achieve the desired goals. If the Company fails to successfully promote and maintain its brands or if the Company incurs excessive expenses in this effort, the Company's business and financial results from operations could be materially adversely affected.

***Success of Quality Control Systems***

The quality and safety of the Company's products are critical to the success of the Company's business and operations. As such, it is imperative that the Company and its service providers' quality control systems operate



effectively and successfully. Quality control systems can be negatively impacted by the design of the quality control systems, the quality training program, and adherence by employees to quality control guidelines. Although the Company strives to ensure that all of its service providers have implemented and adhere to high-caliber quality control systems, any significant failure or deterioration of such quality control systems could have a material adverse effect on the Company's business and operating results.

#### ***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.

#### ***Inability to Implement the Business Strategy***

The growth and expansion of Revive's business is heavily dependent upon the successful implementation of Revive's business strategy. There can be no assurance that Revive will be successful in the implementation of its business strategy.

#### ***Uninsured or Uninsurable Risk***

The Company may become subject to liability for risks which are uninsurable or against which the Company may opt out of insuring due to the high cost of insurance premiums or other factors. The payment of any such liabilities would reduce the funds available for usual business activities. Payment of liabilities for which insurance is not carried may have a material adverse effect on the Company's financial position and 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.

#### ***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.

## **AUDIT COMMITTEE**

The audit committee of the Board ("**Audit Committee**") is responsible for monitoring the Company's systems and procedures for financial reporting and internal control, reviewing certain public disclosure documents and monitoring the performance and independence of the Company's external auditors. The committee is also responsible for reviewing the Company's annual audited financial statements, unaudited quarterly financial statements and management's discussion and analysis of financial results of operations for both annual and interim financial statements and review of related operations prior to their approval by the full Board.

### **Audit Committee Charter**

The full text of the charter of the Audit Committee is attached hereto as Appendix "B".

### **Composition of the Audit Committee**

The Audit Committee members are Craig Leon, Carlo Sansalone, and William Jackson, each of whom is a director, and considered financially literate. Both Mr. Sansalone and Jackson are independent in accordance with NI 52-110.

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**

The following table summarizes the relevant education and experience of the members of the Audit Committee:

<b>Name of Member</b>	<b>Education</b>	<b>Experience</b>
Craig Leon	B.A., McGill University (1990); M.B.A., York University (1993).	Mr. Leon brings extensive financial management and risk assessment experience to the Audit Committee. He served as CEO and Chairman of the board of directors of Titan Medical Inc., a publicly-listed medical device company from July 2008 to March 2013, and as CFO and COO of Redwood Asset Management Inc. from August 2003 to July 2009. Mr. Leon has held a variety of financial analysis and management positions, and has acted as a consultant for evaluating strategic investment opportunities and potential acquisition candidates. As such, he has experience in preparing, analyzing and evaluating financial statements
Carlo Sansalone	B.Comm., Ryerson University (2000).	Mr. Sansalone has acquired knowledge of effective financial management best practices and an understanding of how to help make a company cost-competitive and profitable through education, and experience as president of Sanscon Construction Ltd.

William Jackson	Undergraduate and Graduate degrees Business and Accounting University of Western Ontario (1980) and University of Windsor (1982)	Mr. Jackson has over 20 years' experience with private and public companies, including senior management positions and directorships, and as such he has a comprehensive understanding of the accounting principles used by such companies to prepare financial statements.
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### Audit Committee Oversight

Since the commencement of the last financial year, there has not been a recommendation of the Audit Committee to nominate or compensate an external auditor that was not adopted by the Board.

### External Auditor Services Fees

The following table discloses the service fees billed to the Company by its external auditor during the last two completed financial years:

<u>Financial Year Ending</u>	<u>Audit Fees<sup>(1)</sup></u>	<u>Audit Related Fees<sup>(2)</sup></u>	<u>Tax Fees<sup>(3)</sup></u>	<u>All Other Fees<sup>(4)</sup></u>
June 30, 2018	\$20,000	Nil	\$4,000	Nil
June 30, 2017	\$15,000	Nil	Nil	Nil

Notes:

- (1) The aggregate fees billed for professional services rendered by the auditor for the audit of the Company's annual financial statements as well as services provided in connection with statutory and regulatory filings.
- (2) The aggregate fees billed for professional services rendered by the auditor and consisted primarily of file quality review fees and fees for the review of quarterly financial statements and related documents.
- (3) Aggregate fees billed for tax compliance, tax advice and tax planning professional services. These services included reviewing tax returns and assisting in responses to government tax authorities.
- (4) No other fees were billed by the auditor of the Company other than those listed in the other columns.

### Exemption

Since the Company is a "venture issuer" pursuant to NI 52-110 (its securities are not listed or quoted on any of the Toronto Stock Exchange, a market in the U.S., or a market outside of Canada and the U.S.), it is exempt from the requirements of Part 3 (Composition of the Audit Committee) and Part 5 (Reporting Obligations) of NI 52-110.

### ADDITIONAL INFORMATION

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

Additional information with respect to the Company, including directors' and officers' remuneration and indebtedness, principal holders of securities of the Company and securities authorized for issuance under equity compensation plans, as applicable, is contained in the Company's information circular dated November 6, 2018 a copy of which has been filed on SEDAR and is available at [www.sedar.com](http://www.sedar.com).

Additional financial information is provided in the Company's audited annual financial statements and the management's discussion and analysis for its most recently completed financial year.

## **APPENDIX “A” GLOSSARY**

In this AIF, the following terms have the following meanings, unless there is something in the context or subject matter inconsistent therewith:

“**ACMPR**” has the meaning ascribed to it in “*Regulatory Overview*”;

“**AIF**” has the meaning ascribed to it in “*Cautionary Note Regarding Forward-Looking Statements*”;

“**AIH**” has the meaning ascribed to it in “*General Development of the Business*”;

“**Amalgamation**” has the meaning ascribed to it in “*Corporate Structure*”;

“**ANDA**” has the meaning ascribed to it in “*Regulatory Overview*”;

“**Audit Committee**” has the meaning ascribed to it in “*Audit Committee*”;

“**August 2016 Offering**” has the meaning ascribed to it in “*General Development of the Business*”;

“**Axim**” has the meaning ascribed to it in “*General Development of the Business*”;

“**Axim Agreement**” has the meaning ascribed to it in “*General Development of the Business*”;

“**BCP**” has the meaning ascribed to it in “*Business of Revive*”;

“**Board**” has the meaning ascribed to it in “*General Development of the Business*”;

“**CBD**” has the meaning ascribed to it in “*General Development of the Business*”;

“**CDSA**” has the meaning ascribed to it in “*Regulatory Overview*”;

“**cGMP**” has the meaning ascribed to it in “*Regulatory Overview*”;

“**CMOs**” has the meaning ascribed to it in “*Risk Factors*”;

“**Company**” has the meaning ascribed to it in “*Cautionary Note Regarding Forward-Looking Statements*”;

“**CSA**” has the meaning ascribed to it in “*Regulatory Overview*”;

“**DEA**” has the meaning ascribed to it in “*Regulatory Overview*”;

“**FDA**” has the meaning ascribed to it in “*General Development of the Business*”;

“**FDA-NDA**” has the meaning ascribed to it in “*Regulatory Overview*”;

“**FDCA**” has the meaning ascribed to it in “*Regulatory Overview*”;

“**February Offering**” has the meaning ascribed to it in “*General Development of the Business*”;

“**Formulation**” has the meaning ascribed to it in “*General Development of the Business*”;

“**GCP**” has the meaning ascribed to it in “*Regulatory Overview*”;

“**HHL**” has the meaning ascribed to it in “*General Development of the Business*”;

“**HHL Transactions**” has the meaning ascribed to it in “*General Development of the Business*”;

“**IND**” has the meaning ascribed to it in “*General Development of the Business*”;

“**IRB**” has the meaning ascribed to it in “*Regulatory Overview*”;

“**IRI**” has the meaning ascribed to it in “*General Development of the Business*”;

“**IT**” has the meaning ascribed to it in “*Risk Factors*”;

“**JVco**” has the meaning ascribed to it in “*General Development of the Business*”;

“**JV LOI**” has the meaning ascribed to it in “*General Development of the Business*”;

“**Mercury**” has the meaning ascribed to it in “*Corporate Structure*”;

“**Mercury AcquisitionCo**” has the meaning ascribed to it in “*Corporate Structure*”;

“**Minister**” has the meaning ascribed to it in “*Regulatory Overview*”;

“**NAFLD**” has the meaning ascribed to it in “*Business of Revive*”;

“**NDS**” has the meaning ascribed to it in “*Regulatory Overview*”;

“**NI 51-102**” has the meaning ascribed to it in “*General Development of the Business*”;

“**NI 52-110**” means National Instrument 52-110 - *Audit Committees* of the Canadian Securities Administrators;

“**NOC**” has the meaning ascribed to it in “*Regulatory Overview*”;

“**OBCA**” has the meaning ascribed to it in “*Corporate Structure*”;

“**Old Revive**” has the meaning ascribed to it in “*Corporate Structure*”;

“**REV-002**” has the meaning ascribed to it in “*General Development of the Business*”;

“**REV-004**” has the meaning ascribed to it in “*General Development of the Business*”;

“**Revive**” has the meaning ascribed to it in “*Cautionary Note Regarding Forward-Looking Statements*”;

“**Revive Inc.**” has the meaning ascribed to it in “*Corporate Structure*”;

“**Richmond**” has the meaning ascribed to it in “*General Development of the Business*”;

“**RTO**” has the meaning ascribed to it in “*Corporate Structure*”;

“**SanyalBio**” has the meaning ascribed to it in “*General Development of the Business*”;

“**SCRF**” has the meaning ascribed to it in “*General Development of the Business*”;

“**SCRF License Agreement**” has the meaning ascribed to it in “*General Development of the Business*”;

“**THC**” has the meaning ascribed to it in “*Business of Revive*”;

“**THCV**” has the meaning ascribed to it in “*Business of Revive*”;

“**TPD**” has the meaning ascribed to it in “*Regulatory Overview*”;

“**TSX-V**” has the meaning ascribed to it in “*Corporate Structure*”;

“**University of Wisconsin-Madison Research Program**” has the meaning ascribed to it in “*General Development of the Business*”;

“**WARF**” has the meaning ascribed to it in “*General Development of the Business*”;

“**WARF License Agreement**” has the meaning ascribed to it in “*General Development of the Business*”;

“**WeedMD**” has the meaning ascribed to it in “*General Development of the Business*”; and

“**WeedMD Agreements**” has the meaning ascribed to it in “*General Development of the Business*”.

Words importing the singular number only include the plural, and *vice versa*, and words importing any gender include all genders. All dollar amounts set forth in this annual information form are in Canadian dollars, except where otherwise indicated.

**APPENDIX “B”  
AUDIT COMMITTEE CHARTER**

**REVIVE THERAPEUTICS LTD.  
(the “Company”)**

**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.