

**REVIVE THERAPEUTICS LTD.**

**MANAGEMENT'S DISCUSSION AND ANALYSIS**

**FOR THE YEAR ENDED JUNE 30, 2017**

## **Introduction**

The following management's discussion and analysis ("MD&A") of the financial condition and results of the operations of Revive Therapeutics Ltd. ("Revive", or the "Company") constitutes management's review of the factors that affected the Company's financial and operating performance for the year ended June 30, 2017. This MD&A was written to comply with the requirements of National Instrument 51-102 – Continuous Disclosure Obligations. This discussion should be read in conjunction with the audited annual financial statements of the Company for the fiscal years ended June 30, 2017 and 2016, together with the notes thereto. Results are reported in Canadian dollars, unless otherwise noted. The Company's financial statements and the financial information contained in this MD&A are prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB") and interpretations of the IFRS Interpretations Committee ("IFRIC"). In the opinion of management, all adjustments (which consist only of normal recurring adjustments) considered necessary for a fair presentation have been included. Information contained herein is presented as at October 19, 2017, unless otherwise indicated.

For the purposes of preparing this MD&A, management, in conjunction with the Board of Directors, considers the materiality of information. Information is considered material if: (i) such information results in, or would reasonably be expected to result in, a significant change in the market price or value of Revive's common shares; (ii) there is a substantial likelihood that a reasonable investor would consider it important in making an investment decision; or (iii) it would significantly alter the total mix of information available to investors. Management, in conjunction with the Board of Directors, evaluates materiality with reference to all relevant circumstances, including potential market sensitivity.

Further information about the Company and its operations can be obtained from the offices of the Company or on SEDAR at [www.sedar.com](http://www.sedar.com).

## **Caution Regarding Forward-Looking Statements**

This MD&A 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 the Company's future performance. 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 statements 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 MD&A speak only as of the date of (i) this MD&A; or (ii) as of the date specified in such statement. The following table outlines certain significant forward-looking statements contained in this MD&A and provides the material assumptions used to develop such forward-looking statements and material risk factors that could cause actual results to differ materially from the forward-looking statements.

**REVIVE THERAPEUTICS LTD.**  
**Management's Discussion & Analysis**  
**For the year ended June 30, 2017**  
**Dated – October 19, 2017**

| Forward-looking Statements   | Assumptions  | Risk Factors   |
|--|--|--|
| <p>The Company's (i) development of new drug candidates, (ii) demonstration of such drug candidates' safety and efficacy in clinical trials, and (iii) obtaining regulatory approval to commercialize these drug candidates.</p> | <p>Financing will be available for development of new drug 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 drug candidates will be received on a timely basis upon terms acceptable to Revive; and applicable economic conditions are favourable to Revive.</p>   | <p>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.</p>   |
| <p>The Company's ability to obtain the substantial capital it requires to fund research and operations.</p>  | <p>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.</p>  | <p>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.</p>  |
| <p>Factors affecting clinical trials and regulatory approval process of the Company's drug candidates.</p>   | <p>Actual costs of 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 clinical studies on a timely basis with favourable results; all applicable regulatory and governmental approvals for drug candidates will be received on a timely basis with terms acceptable to Revive; debt and equity markets, exchange and interest rates, and other applicable economic and political conditions are favourable to Revive; there will be a ready market for the drug candidates.</p> | <p>Revive's drug candidates may require time-consuming and costly preclinical and clinical 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 competition.</p> |

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| Forward-looking Statements   | Assumptions   | Risk Factors  |
|--|---|---|
| The Company's ability to find and enter into agreements with potential partners to bring viable drug candidates to commercialization.                  | Revive will be able to find a suitable partner and enter into agreements to bring drug candidates to market within a reasonable time frame and on favourable terms; the costs of entering into a partnership will be consistent with Revive's expectations; partners will provide necessary financing and expertise to bring drug candidates to market successfully and profitably.   | Revive will not be able to 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 drug 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 drug 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 drug 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 therapeutics with regards to cannabinoids, gout, cystinuria, Wilson's disease, rare diseases, pain, inflammatory skin diseases, liver diseases, 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 the Company'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 MD&A.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company'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.

## **Description of Business**

The Company is a reporting issuer in the provinces of British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island and Newfoundland. Its common shares are listed for trading on the TSX Venture Exchange under the symbol "RVV" and on the OTCBB under the symbol "RVVTF". The Company's registered and head office is located at 5 Director Court, Suite 105, Vaughan, Ontario, L4L 4S5 and its website is available at [www.revivetherapeutics.com](http://www.revivetherapeutics.com).

### *Overview:*

The Company is focused on the research, development and commercialization of novel treatments for serious and unmet medical needs by identifying and investigating potential therapies targeting the endocannabinoid system, such as cannabinoids, that may be repurposed for new indications, be delivered in a different way, combined with existing drugs, or be developed as new chemical entities.

We have expertise in preclinical and clinical research, regulatory, and commercial development activities. Our goal is to use these core competencies to advance our product candidates along the regulatory and clinical pathway toward commercial approval. We believe we have the ability to manage and perform the key critical aspects of the drug development process, including conducting or managing preclinical studies, clinical trials, developing and executing strategies for the protection of intellectual property, and interacting with regulatory authorities. We are actively seeking development and commercial partnerships that might facilitate these activities. In the meantime, we are prepared to advance our drug candidates toward commercial approval in the most efficient and expeditious manner.

Our initial focus was on the advancement of repurposing the drug Bucillamine, an arthritis drug approved only in Japan and South Korea, for the treatment of gout (pain from flares). We have completed a Phase 2a clinical program with Bucillamine in acute flares and we are currently seeking funding, development, and commercialization partners to advance into Phase 2b and into registration studies. We are also investigating Bucillamine as a potential treatment for cystinuria (kidney stones). We initiated the U.S. Phase 2 clinical study in February 2017 and began enrolling subjects in May 2017. We expect to complete the study in 2018.

To expand our product pipeline, we employ bioinformatics to perform scientific evaluation, clinical, and market assessment of potential pharmaceutical products for diseases that fall into our target area of expertise. Subsequently, we have also focused on expanding our product pipeline through the advancement of our cannabinoid-based therapeutics strategy in, but not limited to, pain, skin disorders, and liver diseases. We initiated a research discovery program of cannabinoid-based therapies targeting liver diseases with PhytoSciences Consulting LLC., a contract research organization. We are also actively engaging in a review of certain complimentary assets that we may consider acquiring or licensing, such as the novel drug delivery technology asset that we optioned from Wisconsin Alumni Research Foundation (WARF). We have engaged with the University of Wisconsin-Madison to conduct research and development on a novel topical drug delivery technology to deliver cannabinoids ("The University of Wisconsin-Madison Research Agreement"). Also, we entered into a license agreement with South Carolina

Research Foundation (“SCRF”), under which we will acquire an exclusive license from SCRF to develop and commercialize a portfolio of patents based on cannabinoid-based therapeutics, such as cannabidiol, in the treatment of liver diseases.

Upon licensing a product candidate, our strategy is to apply our expertise and our 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 clinical data, and submitting such data to the relevant regulatory authorities in compliance with applicable protocols and standards.

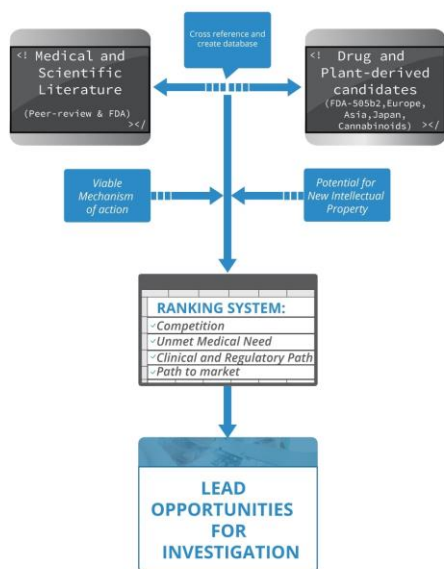
We may also develop next-generation versions of our drug candidates, which will aim to improve upon the original drug or cannabinoid, and may have the potential to treat new diseases that would otherwise remain untreated by the original drug.

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

In order to optimize the development of our product candidates, we outsource certain aspects of our research and product development activities. Factors that we consider in determining which activities to outsource include cost, relative expertise, capacity, and quality assurance. Product development functions that we have chosen to historically outsource include pre-clinical activities in support of regulatory filings, clinical trials, and manufacturing. We believe that our relationships with external laboratories enable us to complete preclinical testing faster and more efficiently than we can perform these activities in-house. Additionally, we have identified many independent contract research organizations (CROs) that are specifically equipped to manage future clinical trial projects, thus alleviating the need for us to commit redundant internal resources. For now, we believe that it is more efficient to outsource drug product manufacturing to contract manufacturing organizations (CMOs) and third-party suppliers.

*Bioinformatics:*

We utilize bioinformatics designed to identify repurposed and innovative compounds for treatment of serious and unmet medical needs. We review scientific literature looking for mechanisms of action that could prove useful for diseases and then rank these drug-disease pairs based on a weighting system that incorporates, but not limited to, clinical studies, FDA correspondence, competition, and unmet medical need.



Graphic representation of bioinformatics approach

## Principle Products

### Bucillamine

Bucillamine is a disease-modifying anti-rheumatic drug, which is prescribed for rheumatoid arthritis in Japan and South Korea. We are repurposing Bucillamine as a potential new treatment for gout and cystinuria.

#### Material Transfer Agreement

Based on animal study results, we focused on advancing the clinical development of bucillamine for the treatment of acute gout flares. We entered into a material transfer agreement (“MTA”) with the developer of bucillamine. Pursuant to the MTA, we would be able obtain access to proprietary and confidential information (i.e. non-clinical data, clinical data, manufacturing information) and clinical trial supply of the drug bucillamine for the phase 2a and phase 2b human clinical studies of bucillamine for the treatment of acute gout flares and cystinuria. In return, the developer of bucillamine will have exclusive commercialization rights in Japan, Korea and Taiwan, and we will have exclusive commercialization rights in the rest of the world.

### Gout

There were 14.3 million diagnosed prevalent cases of chronic gout in the major pharmaceutical markets in 2012, which is forecast to increase to 17.7 million by 2021 (Source: *Decision Resources 2012*). Gout in the U.S. affects approximately 8.3 million (~3.9%) of American adults (Source: *Arthritis Rheum. 2011 Oct; 63(10):3136-41*). It is estimated that the gout disease treatment market value will increase from \$989 million in 2013 to \$2.28 billion by 2018 (Source: *GlobalData 2014*). Gout is a painful disorder caused by elevated serum uric acid (sUA) in the body due to under excretion of uric acid and/or over production of uric acid. Most patients on the most commonly employed regimens for uric acid lowering fail to achieve a satisfactory serum urate level. Poor control of gout can lead to acute attacks of severe pain, and chronic joint damage and impairment of health related quality of life. Accordingly, there are needs in the market for new therapies to control gouty inflammation and hyperuricemia.



Although gout is a treatable condition, there are limited treatment options, many of which have adverse side effects. Drug treatment for gout includes anti-inflammatory agents (non-steroidal anti-inflammatories (NSAIDs), corticosteroids, Colchicine) and serum urate-lowering therapies, which work by lowering body stores of uric acid. Treatment of gouty inflammation is complicated by the fact that gout patients have a high incidence of cardiovascular and metabolic comorbidities. Common comorbidities include hypertension (70-80%), coronary artery disease (>30-40%), chronic kidney disease (~30-50%), diabetes (~25-40%), gastrointestinal tract diseases, and congestive heart failure (Source: Keenan, RT et. al., *Prevalence of contraindications and prescription of pharmacologic therapies for gout. Am. J. Med. 2011, 124: 155-163*). Managing patients with these comorbidities is challenging because the majority of them have contraindication for one or more first-line approved medications to treat acute gout. Current drug therapy limitations include: 90% of gout patients having at least one contraindication to NSAIDs and glucocorticoids; 50% to 66% having at least one contraindication to Colchicine. Moreover, corticosteroids can cause hypertension and worsening of blood sugar, and NSAIDs have substantial renal and cardiovascular toxicity.

#### *Rationale of bucillamine for gout*

Gout is a common disorder characterized by accumulation of excess body stores of uric acid, and by acute inflammatory attacks of arthritis, and in some patients a chronic destructive arthritis, stimulated by crystalline deposits of the sodium salt of uric acid (monosodium urate) in joint tissues. Bucillamine is a thiol donor derived from the amino acid cysteine, and is similar to N-acetylcysteine and N-2-mercaptopyrionyl glycine. (Source: *Proc. Natl. Acad. Sci. USA 2002, 99: 8915-8920; J. Immunol. 2002, 168: 2560-2567*). However, relative to these comparators, bucillamine contains two donatable thiol groups rather than one. It is therefore a considerably more potent inhibitor of certain oxidative stress-triggered cell signalling events that promote acute and chronic inflammation, and are implicated in the painful arthritis of acute gout flares. (Source: *J. Immunol. 2000, 165: 2703—2711; J. Cardiovasc. Pharmacol. 2001, 38: 859-867; Cardiovasc. Drug Rev. 2003, 21: 77-90*).

In addition to its direct action on oxidative stress-induced inflammation signalling, bucillamine acts to stimulate the cellular production of proteins that can regulate the level of uric acid excretion by the kidney, and thereby, their capacity to lower the serum level of uric acid. It does so by increasing the activity of Nuclear factor (erythroid-derived 2)-like 2 (Nrf2), a transcription factor which promotes expression of the urate transporter protein, ATP-binding cassette sub-family G member 2 (ABCG2), which in turn enables uric acid excretion. (Source: *Biochem. Pharmacol. 2006, 72: 455-462; Drug Metab. Dispos. 2006, 34: 1756-1763*). The physiological importance of ABCG2 in humans is illustrated by the large differences in uric acid levels and the prevalence of gout caused by genetic variation in ABCG2. It is therefore, a potential target for new uricosuric agents in the treatment of gout (Source: *Proc. Natl. Acad. Sci. USA. 2009, 106: 10338-10342; Sci. Transl. Med. 2009, 1: 5ra11*). A third mechanism by which bucillamine could potentially affect serum uric acid levels in gout involves another uric acid excretion protein, ATP-binding cassette sub-family C member 4 (ABCC4), which is present in the kidney. Expression of ABCC4 also is promoted by Nrf2. (Source: *J. Pharmacol. Exp. Ther. 2010, 335: 2-12*)

Based on these studies, it was hypothesized that a combination of allopurinol and an Nrf2 activator such as bucillamine may have a synergistic effect in lowering uric acid levels, and that such a combination therapy including primary anti-inflammatory effects with potential secondary uric acid-lowering effects would offer new, more-effective options for gout treatment than other therapies that are currently available.

#### *Preclinical research of bucillamine for gout*

The unpublished animal studies, which served as part of the bucillamine patent for gout, show that:

1. Bucillamine had a highly significant ( $p < 0.001$ ) dose-response effect on monosodium urate crystal-induced release of interleukin-1beta from inflammatory white blood cells *in vitro*. Interleukin-1beta is a principal driving factor for gouty inflammation *in vivo*.



2. Bucillamine had a highly significant ( $p < 0.001$ ) dose-response effect on monosodium urate crystal-induced peritoneal inflammation *in vivo*, which decreased mean neutrophil influx by 5.15% for every increase of 1  $\mu\text{mol/kg}$  of the drug. Neutrophils are a type of inflammatory white blood cell; a reduction in their influx denotes a reduction in inflammation.
3. The effects of the administration of Bucillamine and colchicine on monosodium urate-induced peritoneal inflammation was found such that the addition of Bucillamine (10  $\mu\text{mol/kg}$ ) produced a highly significant ( $p < 0.001$ ) decrease in average neutrophil influx. In addition, there was an interactive relationship between Bucillamine and colchicine such that the addition of Bucillamine enhanced the dose-response effect so that there was a decrease of 32.2% for every increase of 1  $\mu\text{mol/kg}$  of colchicine.
4. There was a significant ( $p = 0.012$ ) interactive effect between Bucillamine and allopurinol on serum and urinary levels of uric acid in a small animal model of elevated uric acid (hyperuricemia). The addition of allopurinol (5mg/kg/day) increased the dose-response effect of Bucillamine so that each increase of 1 mg/kg/day of REV-002 resulted in a decrease of 0.0010 mg/dL in the serum urate concentration.
5. There was a highly significant ( $p < 0.001$ ) interactive effect between allopurinol and Bucillamine on the urinary excretion of uric acid in a small animal model of hyperuricemia. The addition of allopurinol (5mg/kg/day) increased the dose-response effect of Bucillamine such that each increase of 1 mg/kg/day of Bucillamine resulted in an increase of 0.171 mg/dL in the urinary uric acid concentration.

Bucillamine is an established anti-inflammatory agent in rheumatoid arthritis that inhibits the capacity of monosodium urate crystals to provoke inflammation. This suggests the potential for bucillamine to be an effective first line anti-inflammatory drug in the management of acute gouty arthritis flares. Additionally, the synergistic effect of Bucillamine with colchicine on monosodium urate crystal-induced inflammation, demonstrated in small animal studies *in vivo*, suggests potential efficacy as an add-on or second line agent in combination therapy for acute gouty arthritis with colchicine and other agents. The animal study also demonstrated that Bucillamine has a synergistic effect in combination with allopurinol in lowering sUA concentrations in a small animal model of hyperuricemia. The potential uricosuric effect of Bucillamine, particularly when used in conjunction with allopurinol, suggests that bucillamine could provide a means to treat gout more effectively than other therapies that are currently available, via combination of primary anti-inflammatory effects with potential secondary uric acid lowering effects.

#### *Clinical Studies*

The execution of the MTA allowed us to submit our Investigational New Drug Application ("IND") to the FDA. In October 2014, we obtained acceptance from the FDA to commence the Phase 2a clinical trial for bucillamine for the treatment of acute gout flares in the U.S.

The Phase 2a study was an open-label, multicenter, active-controlled, parallel-group clinical trial designed to evaluate the safety and efficacy of two arms of Bucillamine 100mg tablet compared with the active comparator Colchicine (dosed acutely using the FDA-approved regimen) in the treatment of subjects with acute gout flares over a seven-day treatment period. A total of 20 clinical sites in the United States participated in the study and a total of 74 subjects who are confirmed with a qualifying severe gout flare attack was randomized into the study. Subjects were randomized in a 1:1:1 allocation ratio to either Arm A (oral Bucillamine - total of 900mg), Arm B (oral Bucillamine - total of 1,800mg) or Arm C (oral Colchicine - total of 1.8mg) over a seven-day treatment period.

The primary efficacy endpoint is the proportion of patients who responded to treatment. Treatment responders are defined as a  $\geq 50\%$  reduction in target joint pain score from baseline at 72 hours post-dose without using rescue drug. The target joint pain score is an 11-point Pain Intensity Numeric Rating Scale (PI-NRS) used to assess joint pain intensity while experiencing a gout flare on a scale from 0 (no pain) to 10 (worst possible pain). The PI-NRS is completed using a diary where the subject is required to circle the most appropriate number that best describes their level of pain in the identified target joint during specific time points.

The objective of the Phase 2a study was to evaluate the safety and tolerability, and the efficacy of two regimens of oral Bucillamine over seven days of treatment compared with Colchicine (Colcrys®) in the treatment of subjects with severe gout flare attack. The primary efficacy endpoint is the proportion of patients who responded to treatment defined as a  $\geq 50\%$  reduction in target joint pain score from baseline at 72 hours post-dose without using rescue drug.

The final primary endpoint results from the Phase 2a study from a total of 74 subjects that had completed the seven-day treatment period are as follows:

- In Arm A (oral Bucillamine - total of 900mg over 7 days), 55% (12/22 subjects) had a  $\geq 50\%$  reduction in target joint pain score from baseline at 72 hours post-dose without using rescue drug;
- In Arm B (oral Bucillamine - total of 1,800mg over 7 days), 46% (11/24 subjects) had a  $\geq 50\%$  reduction in target joint pain score from baseline at 72 hours post-dose without using rescue drug;
- In Arm C, the active comparator arm, (oral Colchicine - 1.8mg over 1 hour), 46% (13/28 subjects) had a  $\geq 50\%$  reduction in target joint pain score from baseline at 72 hours post-dose without using rescue drug; and
- Bucillamine was well tolerated and there were no serious adverse events reported in subjects taking Bucillamine.

Overall, these exploratory results demonstrate that bucillamine has a signal of efficacy similar to that observed with the comparator drug, Colchicine (Colcrys®), in this clinical study, which has been previously approved for this indication in the U.S.

#### *Future Non-clinical and Clinical Studies*

Based on the Phase 2a study results, we designed a potentially pivotal Phase 2b, adequate and well-controlled, multicenter, double blinded, placebo controlled trial and submitted the Phase 2b protocol to the FDA. The FDA has accepted the Phase 2b protocol and we are able to proceed with the study. Once we complete the Phase 2b study, we will submit for an end-of-Phase 2 meeting with the FDA to discuss Phase 3 study plans, additional human clinical studies and any non-clinical studies that the FDA may require us to perform prior to submitting the new drug application for commercial approval in the U.S.

#### *Intellectual Property*

On June 2013, we were assigned the rights to the patent application No. AU2012905072 from Xenexus Pharmaceuticals Pty, which was replaced by U.S. patent No. 9,238,018, titled 'The Use of Bucillamine in the Treatment of Gout' which was then subsequently replaced by U.S. patent No. 9,662,305 and expires in late 2033.

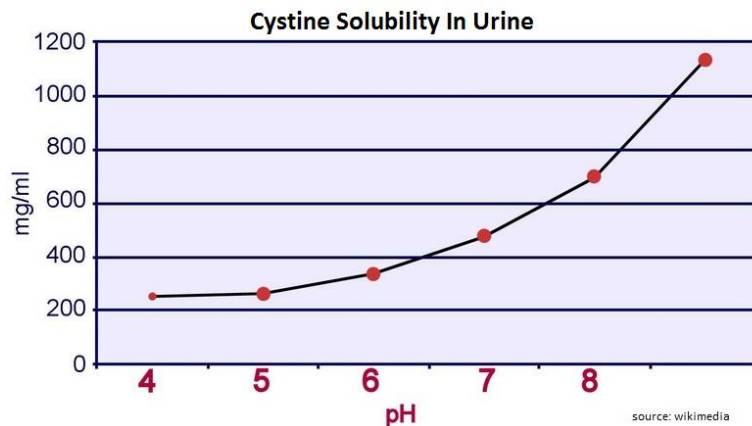
#### **Cystinuria**

Cystinuria is a rare autosomal recessive genetic disorder that causes high levels of cystine in the urine thus causing kidney stones to form. The resulting kidney stones are often large and recurrent and lead to significant morbidity and sometimes loss of kidney function. The important clinical manifestation of the disease is a build-up of cystine in the urine, which in turn results in crystallization and stone formation in

the kidneys and bladder. In healthy individuals, most cystine dissolves and returns to the bloodstream after entering the kidneys. People with cystinuria have the aforementioned genetic defects that interfere with this process. No curative treatment of cystinuria exists, and typically patients have a lifelong risk of stone formation, repeated surgery, and impaired renal function. There are approximately between 10,000 and 12,000 patients affected with cystinuria in the U.S. The worldwide prevalence is about 1 in 7,000.

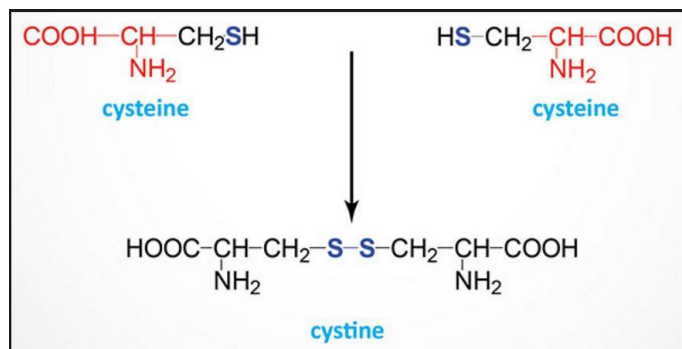
Therapy to reduce stone formation focuses on lowering urine cystine concentration and increasing cystine solubility. Cystine is poorly soluble in urine and prone to crystallization and stone formation at concentrations above 300 mg/l. As such, the primary non-pharmacological intervention for preventing cystine stones is to increase fluid intake. Patients with cystinuria are recommended to drink at least three liters of fluid a day (equivalent of ten 10 oz. glasses of water).

The solubility of cystine is also highly dependent on pH. At physiological pH (~7) maximum cystine solubility is between 200 and 400 mg/l. Acidic urine (pH of 5) greatly reduces the solubility to below 250 mg/l; however, at pH greater than 7.5 the solubility increases exponentially. In fact, the solubility of cystine doubles to 500 mg/l at pH 7.5. Unfortunately, excessive alkali therapy is not advisable. When urinary pH increases above 7.0 with alkali therapy, the complication of calcium phosphate nephrolithiasis may ensue because of the enhanced urinary supersaturation of hydroxyapatite in an alkaline environment.



Increase fluid intake and alkali therapy are not always feasible or effective. In fact, work published by researchers from Duke University found that therapeutic success with these more conservative approaches, defined as a urine cystine concentration below 300 mg/l, was achieved by only 15% of patients treated at the University Medical Center over an eight-year period. For patients that cannot reduce stone formation on these conservative programs, pharmaceutical intervention is recommended. The two leading pharmaceutical products for the treatment of cystinuria are Retrophin's Thiola® (tiopronin) and Valeant's Cuprimine® (d-penicillamine).

Penicillamine is a first-line chelating agent use for the removal of excess copper in patients with Wilson's disease and to reduce excess cystine in patients with cystinuria. The mechanism of action for cystine reduction is by disulfide interchange between d-penicillamine and cystine, resulting in the formation of penicillamine-cysteine disulfide, a substance that is much more soluble than cystine and readily excreted. Cystine is a combination of two cysteine (cys) amino acids whose thiol side chains have been oxidized to form cystine.



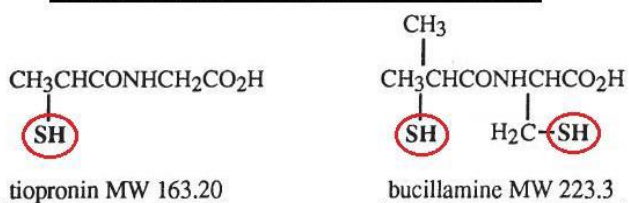
Cystine is far less soluble than cysteine and thus creates problems at urine concentrations above 300 mg/l. Penicillamine competes with excess cysteine to form penicillamine-cysteine disulfide, a far more soluble compound (roughly 50x more so) than cystine. Penicillamine also deprotonates cystine to form penicillamine-cysteine disulfide. The drug is highly effective in the treatment of cystinuria but has poor tolerability and serious safety concerns. The use of penicillamine has been associated with fatalities due to certain diseases such as aplastic anemia, agranulocytosis, thrombocytopenia, Goodpasture's syndrome, and myasthenia gravis. The incidence of adverse events ranges between 30% and 60%.

Tiopronin received FDA approval in 1988 for the prevention of cystine stone formation in patients with severe homozygous cystinuria with urinary cystine greater than 500 mg/day, who are resistant to treatment with conservative measures of high fluid intake, alkali and diet modification, or who have adverse reactions to penicillamine. Tiopronin has similar efficacy and mechanism of action to penicillamine. Tiopronin is an active reducing agent which undergoes thiol-disulfide exchange with cystine to form a mixed disulfide of tiopronin-cysteine. The drug is ideal for patients with allergic reactions or intolerance to penicillamine and considered to be the most tolerable of the two drugs.

Tiopronin has serious side effects including aplastic anemia, agranulocytosis, thrombocytopenia, Goodpasture's syndrome or myasthenia gravis. Patients on the drug should have peripheral blood counts, platelet counts, hemoglobin, serum albumin, and urinary protein levels checked on a regular basis. Patients are also advised to have liver function tests and abdominal roentgenograms on a yearly basis.

#### Rationale of buccillamine for cystinuria

##### Chemical structure of tiopronin and buccillamine

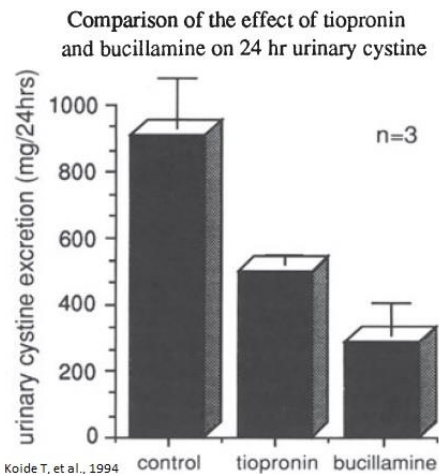


As noted above, buccillamine has been used in Japan and Korea for decades in the majority of cases for the treatment of rheumatoid arthritis. Researchers out of Osaka University School of Medicine conducted *in vitro* and *in vivo* studies during the early 1990s that provide excellent proof-of-concept of Buccillamine for the treatment of cystinuria.

*In vitro study:* The effects of buccillamine compared to tiopronin was tested in whole urine by adding l-cysteine at a concentration of 500 µg/mL along with half and equal concentrations of the two study drugs. Results show that the concentration of cystine was markedly reduced by both tiopronin and buccillamine due to the formation of cysteine-tiopronin or cysteine-buccillamine; however, the relative activity of buccillamine was 5

to 12% stronger than that of tiopronin and calculated the relative molecular activity of bucillamine was approximately 40 to 50% stronger than that of tiopronin. In other words, the data shows bucillamine dissolved urinary cystine much more effectively than tiopronin at the same molecular weight and a little more effectively than tiopronin at the same drug concentration.

*In vivo study:* Japanese researchers then tested bucillamine and tiopronin in three patients with confirmed cystinuria in a controlled, two-way, cross-over, wash-out design study of identical doses of each drug. The effectiveness of bucillamine was compared with tiopronin by analyzing the 24-hour urine samples under three different conditions: control, bucillamine, and tiopronin. The data show both bucillamine and tiopronin were effective in reducing urinary cystine concentration at 24 hours but that bucillamine was statistically superior (markedly superior in two patients and slightly superior in the third).



Although a small study, the work by Koide T., et al., 1994 does provide proof-of-concept for Revive Therapeutics in the planned Phase 2 study. The authors concluded, "Bucillamine can dissolve cystine approximately twice as effectively as tiopronin at the same mg amount."

Based on these exploratory results, the information regarding bucillamine, whereby bucillamine has a chemical structure similar to Thiola®, but has two active thiol groups versus only one for Thiola®, and the MTA we have in place for bucillamine we focused on advancing the clinical development of bucillamine for the treatment of cystinuria. We believe that bucillamine may offer patients a safer, more effective treatment option that either of the two monothiol drugs, tiopronin or d-penicillamine. Theoretically, bucillamine should be twice as effective as tiopronin at the same concentration or equally as effective at lower concentrations, potentially making the drug more tolerable to patients.

#### *Clinical status*

On July 6, 2016, we obtained acceptance of our IND from the FDA to commence the Phase 2 clinical trial for bucillamine for the treatment of cystinuria. The Cystinuria Phase 2 study is a multi-center, dose escalation trial to assess the safety and effectiveness of bucillamine on urinary cystine excretion and cystine capacity in patients with Cystinuria. The primary outcome measures are the incidence of treatment-emergent adverse events along with secondary outcome measuring 24-hr urine cysteine excretion and 24-hr urine cystine capacity, i.e., the capacity of a patient's urine to solubilize or precipitate. The study plans to enroll up to 30 subjects in at least 5 clinical sites in the U.S. We initiated the U.S. Phase 2 clinical study in February 2017 and began enrolling subjects in May 2017. We expect to complete the study in 2018.

#### *Future Non-clinical and Clinical Studies*

Based on the Phase 2 study results we will submit for an end-of-Phase 2 meeting with the FDA to discuss a Phase 3 study, additional human clinical studies, and non-clinical studies that the FDA may require us to perform prior to submitting the new drug application for commercial approval in the U.S.

#### *Market exclusivity*

On October 26, 2015 we announced that the Office of Orphan Products Development of the U.S. Food and Drug Administration (US FDA) has granted orphan designation status for the use of the drug bucillamine for the treatment of cystinuria. Orphan drug designation is granted to therapeutics treating rare diseases affecting less than 200,000 people in the U.S. The orphan drug designation qualifies the Company for various incentives such as a seven-year period of marketing exclusivity in the U.S., the potential for expedited drug development, and opportunities for drug grants and assistance in clinical research study design from the U.S. FDA.

#### **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 cannabidiol (CBD). It is widely known that THC is a major psychoactive cannabinoid and is a partial agonist of the cannabinoid receptor type 1 (CB<sub>1</sub>) and cannabinoid receptor type 2 (CB<sub>2</sub>) 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 preclinical 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 skin disorders and liver diseases.

Due to the mounting data from preclinical 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™ (GW Pharma), Marinol™ (AbbVie), Cesamet™ (Meda), and dronabinol, a synthetic THC (Insys). There are many companies supplying synthetic cannabinoids, cannabis extracts, and herbal cannabis to researchers for preclinical 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, arthritis patients. The cannabinoid-based therapeutics market is expected to grow significantly due to the potential benefits these products may provide over existing therapies.

#### *Drug delivery technology strategy*

The Company is focused on developing a novel drug delivery technology to effectively deliver cannabinoids through the skin and/or directly into the affected area of the skin, otherwise known as transdermal delivery. The potential advantages of transdermal delivery of cannabinoids are that it avoids gastrointestinal tract difficulties, avoids first-pass liver metabolism, enables a steady blood-level profile resulting in improved efficacy over other dosage forms, improves patient compliance as it is user-friendly, convenient, painless, and offers multi-day dosing.

The Company will initially explore the development of a CBD hydrogel, which may have the potential to be delivered in a controlled or sustained release fashion, systemically or locally, through the skin. Transdermal gels are designed to deliver sustained drug amounts, resulting in systemically consistent levels.



#### *Proposed transdermal drug delivery technology*

The Company's transdermal drug delivery technology, a proposed topical hydrogel, will initially deliver CBD, which has anti-inflammatory and analgesic properties, in combination with chitosan and tannins, the two major components of the transdermal drug delivery system. The chitosan has blood-clotting and antimicrobial properties and tannins have antibacterial, antifungal, antioxidant and wound healing properties. The combination of CBD, chitosan and tannins is believed to have synergistic effect and become the next generation drug delivery solution for cannabinoids to treat a wide variety of diseases such as, but not limited to, neuropathic pain and various skin disorders (i.e. acne, psoriasis).

#### *Wisconsin relationship*

The transdermal drug delivery technology was founded and based out of the University of Wisconsin. The Company has engaged in a Research and Option to License agreement with the Wisconsin Alumni Research Foundation (WARF) to advance the development of the technology with cannabinoids for treatment of pain. Likewise, we have engaged with the University of Wisconsin-Madison to conduct research and development on a novel topical drug delivery technology to deliver cannabinoids ("The University of Wisconsin-Madison Research Agreement") for the potential treatment of various diseases.

#### *Potential indications*

The Company is expanding its product pipeline with novel cannabinoid-centric treatments for pain, skin disorders, and liver diseases. Cannabinoids are a class of compounds derived from cannabis plants. The two well-known cannabinoids contained in cannabis are CBD and THC. For pain and skin disorders, Revive is focused on developing a novel topical hydrogel designed to safely and effectively deliver cannabinoids through the skin. Initially, the Company will develop CBD hydrogel and establish proof-of-concept unlocking the potential to treat pain, such as neuropathic or joint pain, and skin disorders, such as inflammatory skin diseases and wound healing, along with rare diseases that exist within these disease areas. For liver diseases, the Company has initiated research into cannabinoids employing a cell-based ligand screening approached with approximately 80 cannabinoids utilizing a number of cell-based assays, which will then be followed by studies in animal models of a number of liver diseases. These experiments will investigate cannabinoids as potential therapeutics for the following liver indications: Liver regeneration, alcoholism, alcoholic steatohepatitis, liver inflammation, liver fibrosis, and non-alcoholic fatty liver disease.

#### *Neuropathic Pain*

According to Decision Resources, in 2017 there are expected to be approximately 15.2 million peripheral neuropathic pain patients in the United States, and pain treatment for these patients are expected to represent a total U.S. market size of approximately \$3.3 billion in 2017.

The Company's next generation topical CBD hydrogel is designed to provide safe, effective, long-term 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, or 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.

Revive's topical CBD hydrogel may have the potential to treat a number of neuropathic pain indication more safely and effectively than that of traditional CBD delivery and current treatments for these indications. It is anticipated that the Revive Topical CBD hydrogel may be used as first- or second-line monotherapy in patients with peripheral neuropathic pain.

Revive's topical CBD hydrogel may also be explored for additional pain disorders in the future.

#### *Inflammatory skin disorders*

Inflammatory skin disorders are the results 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. 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 B market, of which 90% are from drugs targeting moderate to severe psoriasis patients where the skin manifestation affects more than 3% of the body.

Revive's topical CBD hydrogel may have the potential to treat a number of inflammatory skin disorders more safely and effectively than that of traditional CBD delivery and current treatments for these indications. It is anticipated that the Revive Topical CBD hydrogel may be used as first- or second-line monotherapy in patients with the various inflammatory skin disorders.

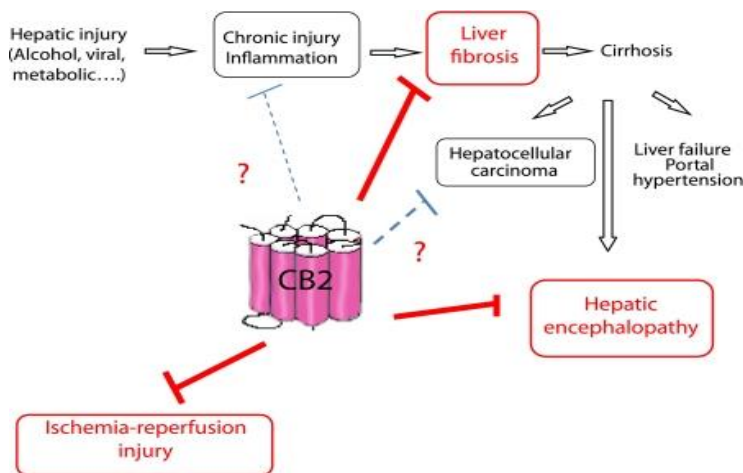
Revive's topical CBD hydrogel may also be explored for additional inflammatory skin disorders and wound healing indications in the future.

#### *Liver diseases*

Liver disease is described by irregular functioning of liver, causing disorders like hepatitis, fatty liver, and cirrhosis. There are over 100 described diseases of the liver affecting at least 30 million people alone in the U.S. 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 (HCV), hepatitis B virus (HBV), 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 Research, titled, "World Liver Disease Treatment Market - Opportunities and Forecast, 2014 - 2022", the global market for liver disease treatment is projected to reach \$19,536 million by 2022.

The Company is in the research and development of next generation or novel uses of cannabinoids for the treatment of a variety of liver diseases. The Company adopted a bioinformatics approach that was undertaken by a third-party research organization, which provided an overview of the diseases treated by cannabinoids. The analysis of the output did provide insight into potential liver targets. The results indicate the use of CB1 receptor antagonists for several liver indications (i.e. Fatty liver). These results lead to a literature investigation into cannabinoids and their potential application in liver diseases, which is presented below, followed by the proposed experimental approach (pre-clinical).

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.



The Company has compiled a detailed literature review to support cannabinoids for a variety of liver diseases.

Research suggests that CB2 agonists have demonstrated to protect against liver I/R injury. Early evidence indicates that a single ultralow dose THC can reduce the apoptotic, oxidative and inflammatory injury induced by hepatic I/R injury. THC may serve as a potential target for therapeutic intervention in hepatic I/R injury during liver transplantation, liver resection and trauma. There is a separate report indicating that the cannabinoid,  $\Delta^8$ -Tetrahydrocannabivarin, prevents hepatic ischemia/reperfusion injury by decreasing oxidative stress and inflammatory responses through cannabinoid CB2 receptors.  $\Delta^8$ -Tetrahydrocannabivarin activated CB2 receptors *in vitro*, and decreased tissue injury and inflammation *in vivo*, associated with I/R partly via CB2 receptor activation. Research has also indicated that the non-psychoactive cannabinoid, cannabidiol, 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 NF- $\kappa$ B activation and TNF- $\alpha$  production in isolated Kupffer cells, likewise the adhesion molecule expression in primary human liver sinusoidal endothelial cells stimulated with TNF- $\alpha$  and attachment of human neutrophils to the activated endothelium. Thus, 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. 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 (EtOH-CPP) 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 has 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 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,  $\Delta^9$ -Tetrahydrocannabivarin (THCV) and CBD, as potential therapeutics to 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.

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. 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 (Lavon, et al., 2003). Another study found that cannabinoids appeared have immunosuppressive and profibrogenic effects in patients with chronic hepatitis C.

#### *Research and Development Programs in Liver Diseases*

The Company initiated a research discovery program of cannabinoid-based therapeutics targeting liver diseases. The research studies, including *in vitro* and *in vivo* pharmacology, are being conducted by PhytoSciences Consulting LLC, a contract research organization in Louisville, Kentucky. The investigation was overseen by academic scientists with over 20 years' experience with expertise in liver disease research. The research program employed an *in vivo* compound screening approach to investigate phytocannabinoids in a fibrosis model utilizing an in-house cell-based screening model. The cell-based ligand screening is a targeted experimental approach that involved approximately eighty phytocannabinoids. The initial screen of phytocannabinoids resulted in the identification of several promising hits, which demonstrated to be effective at preventing the activation of the cells by Transforming growth factor-beta (TGF- $\beta$ ), thus serving as potential therapeutics for liver fibrogenesis. In the pathological process of liver fibrosis, TGF- $\beta$  plays as a master profibrogenic cytokine in promoting activation and myofibroblastic differentiation of hepatic stellate cells, a central event in liver fibrogenesis. Continuous and/or persistent TGF- $\beta$  signalling induces sustained production of the extracellular matrix components and of tissue inhibitor of metalloproteinase synthesis. Therefore, the regulation of locally activated TGF- $\beta$

levels is increasingly recognized as a therapeutic target for liver fibrogenesis. The results of the Company's research efforts demonstrate that the ligands in question may serve as a novel treatment for liver fibrogenesis and warrant further investigation in animal models. Based on the results of the compound screen, the Company is investigating a number of preclinical studies options for specific liver diseases. The overall objective of these studies is to identify cannabinoids for the potential treatments of a number of well-known and rare diseases that the Company may advance to the clinic and potentially partner with pharmaceutical companies.

The Company entered into a license agreement with the South Carolina Research Foundation ("SCRF"), under which Revive will acquire an exclusive license from SCRF to develop and commercialize a portfolio of patents based on cannabinoid-based therapeutics, such as cannabidiol, in the treatment of 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, autoimmune hepatitis and alcoholic liver disease), activated T lymphocytes and macrophages appear to play an important role in liver damage. Autoimmune hepatitis 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 autoimmune hepatitis (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 autoimmune hepatitis 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 cannabidiol in relevant autoimmune hepatitis animal models. The overall objective is to support cannabidiol for the potential treatment of autoimmune hepatitis that the Company may advance to the clinic and potentially partner with pharmaceutical companies.

Revive is also exploring and conducting due diligence of novel cannabinoid treatments and pharmaceutical treatments for liver diseases.

#### Other Development Programs

The Company is no longer advancing REV-001 (Respiratory Depression) and REV-003 (Rett Syndrome). The Company returned the rights to REV-001 and REV-003 to Numedicus Limited and the Company entered into a data assignment agreement with Numedicus, whereby Numedicus paid the Company an undisclosed fee for the rights to the data for REV-001 and REV-003.

On February 21, 2017, the Company and InMed Pharmaceuticals Inc. ("InMed") entered into a non-binding term sheet agreement contemplating a relationship, pursuant to the signing of definitive agreement within 30 days of the execution of the non-binding term sheet, for the discovery and development of cannabinoid-based therapies targeting kidney diseases. A definitive agreement was not signed within the 30-day period and on May 29, 2017, negotiations were discontinued and an upfront payment of \$10,000 was returned to the Company.

The Company is not dedicating any resources in advancing the development of REV-005 (Bucillamine for the treatment of Wilson disease) at this time.

The following chart summarizes the Company's product candidates, including the principal disease or indication being targeted, clinical trial status, expected milestones and marketing rights for each program:

**REVIVE THERAPEUTICS LTD.**  
**Management's Discussion & Analysis**  
**For the year ended June 30, 2017**  
**Dated – October 19, 2017**

| <b>Program</b>  | <b>Status</b>   | <b>Next Milestone</b>   | <b>Spent For Years Ended 2016/2017</b>  | <b>Estimated Cost to Complete as of (2017)</b> | <b>Marketing Rights</b>                               |
|---|---|---|---|--|---|
| Cannabinoids for liver diseases                         | Completed cell-based ligand screening of cannabinoids with PhytoSciences<br><br>Signed License Agreement with South Carolina Research Foundation                              | Initiate research in various animal models of liver diseases<br><br>Initiate preclinical research in relevant auto-immune hepatitis preclinical models  | Approximately \$84,000 was spent during the year ended June 30, 2017<br><br>Approximately \$nil was spent during the year ended June 30, 2016       | \$nil  | Worldwide   |
| Drug delivery of Cannabinoids                           | Signed Research and License Option agreement with Wisconsin Alumni Research Foundation (WARF)<br><br>Signed Sponsored Research agreement with University of Wisconsin-Madison | Complete chemistry and material science to evaluate hydrogel formulations<br><br>Complete in vitro studies to evaluate hydrogel formulations anti-inflammatory response in RAW macrophage model | Approximately \$9,000 was spent during the year ended June 30, 2017<br><br>Approximately \$nil was spent during the year ended June 30, 2016        | \$207,000                                      | Worldwide   |
| REV-002: Bucillamine for treatment of acute gout flares | Phase II-A human proof of concept study completed; Phase II-A human proof of concept study close out procedures ongoing; FDA allowed for Phase II-B study to proceed.         | Close out Phase II-A human proof of concept study (expected by June 2018)<br><br>Budget beyond 2017 will be determined after a partner via out-licensing or acquisition is completed            | Approximately \$51,000 was spent during the year ended June 30, 2017<br><br>Approximately \$1,516,950 was spent during the year ended June 30, 2016 | Revised budget for year 2018 - \$64,000        | Revive (Rest of world) / MTACo (Japan, Korea, Taiwan) |
|   |   | Partner via out-licensing or acquisition or continue clinical development (date of completion is undetermined)  | N/A   | N/A  |   |



**REVIVE THERAPEUTICS LTD.**  
**Management's Discussion & Analysis**  
**For the year ended June 30, 2017**  
**Dated – October 19, 2017**

| Program  | Status  | Next Milestone   | Spent For Years Ended 2016/2017   | Estimated Cost to Complete as of (2017) | Marketing Rights   |
|--|---|--|---|---|--|
| REV-004: Bucillamine for treatment of cystinuria | Investigational New Drug ("IND") application accepted by the FDA; Initiated Phase II-A human proof of concept study | Complete or decision to continue Phase II-A human proof of concept study (expected December 2017)              | Approximately \$264,000 was spent during the year ended June 30, 2017<br><br>Approximately \$43,000 was spent during the year ended June 30, 2016 | \$716,000                               | 7-year US marketing exclusivity based on orphan drug designation that was awarded by the FDA |
|  |   | Partner via out-licensing or acquisition or continue clinical development (date of completion is undetermined) |   |   |  |

### Operations Highlights

During the year ended June 30, 2017, the Company focused primarily on the initiation of the Phase II clinical study of REV-004, the evaluation and close-out of the Phase II-A study of REV-002, and on the evaluation, research, expansion, and partnering of cannabinoid-based therapeutics.

On July 5, 2016, Revive announced the appointment of Craig Leon, Revive's Chairman of the Board, as Chief Executive Officer ("CEO"). Fabio Chianelli, Revive's former CEO, will continue as President. These changes will permit Mr. Leon to dedicate his efforts to executing the Company's capital markets and business development strategies, while permitting Mr. Chianelli to focus on directing the Company's corporate operations, research, and development programs.

On August 18, 2016, the Company completed a non-brokered private placement of units ("Units") for gross proceeds of \$1,500,000 (the "Offering"). Pursuant to the Offering, the Company issued 15,000,000 Units at \$0.10 per Unit. Each Unit consists of one common share and one-half of one common share purchase warrant (a "Warrant"). Each whole Warrant entitles the holder to acquire one common share for \$0.18 until June 18, 2018 (the "Warrant Expiry Date"). In the event that the volume-weighted average trading price of the Common Shares on the Exchange exceeds \$0.25 per Common Share for any period of 20 consecutive trading days, the Company may, at its option, within five business days following such 20-day period, accelerate the Warrant Expiry Date by delivery of notice to the registered holders thereof and issuing a Warrant Acceleration Press Release, and, in such case, the Warrant Expiry Date shall be deemed to be 5:00 p.m. (Toronto time) on the 30th day following the later of (i) the date on which the Warrant Acceleration Notice is sent to Warrant holders, and (ii) the date of issuance of the Warrant Acceleration Press Release. The fair value of the Warrants was estimated to be \$330,000 using a valuation model incorporating Black-Scholes on the following assumptions: dividend yield of 0%; volatility of 110.10%; risk-free interest rate of 0.56%; and expected life of 1.83 years.

In connection with the Offering, the Company paid \$126,139 in cash finder's fees and other transaction costs of which, \$103,066 was allocated to share capital and \$23,073 was allocated to the Warrants. The Company also issued 492,450 finder's warrants ("Finder's Warrants") to qualified arm's length finders. Each Finder's Warrant entitles the holder to acquire one Unit for \$0.10 until June 18, 2018. The fair value of the Finder's Warrants was estimated to be \$26,900 using a valuation model incorporating Black-Scholes on

**REVIVE THERAPEUTICS LTD.**  
**Management's Discussion & Analysis**  
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**Dated – October 19, 2017**

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the following assumptions: dividend yield of 0%; volatility of 110.10%; risk free interest rate of 0.56%; and expected life of 1.83 years.

On November 2, 2016, the Company announced that it named Dr. David S. Goldfarb, MD, as Principal Investigator of Revive's upcoming Phase 2 clinical study for Cystinuria.

On December 6, 2016, the Company announced positive final study results of REV-003 from its research collaboration with Rettsyndrome.org for the potential treatment of Rett syndrome.

On December 21, 2016, the Company announced it has engaged NYU School of Medicine as one of the Company's clinical sites in the U.S. for its Phase 2 clinical study for Cystinuria.

On January 12, 2017, the Company announced it has engaged Massachusetts General Hospital as one of the Company's clinical sites in the U.S. for its Phase 2 clinical study for Cystinuria.

On January 24, 2017, the Company announced Dr. Pritesh Kumar will join the Company as a Scientific Advisor for cannabinoid-based therapeutics for the Company.

On February 7, 2017, the Company announced the initiation of a Phase II clinical study in patients with cystinuria in the U.S. The initiation of the Phase II clinical study for cystinuria follows Revive's recent announcement that the US FDA has accepted the Company's IND Application to commence a clinical trial for REV-004 (Bucillamine) for the treatment of cystinuria.

On February 16, 2017, the Company announced that it is expanding its product pipeline through the development of cannabinoid-based therapeutics targeting liver diseases.

On February 22, 2017, the Company entered into a non-binding term sheet agreement with InMed Pharmaceuticals Inc. for the discovery and development of cannabinoid-based therapies targeting kidney diseases.

On March 1, 2017, the Company announced the initiation of the research discovery program of cannabinoid-based therapeutics targeting liver diseases.

On March 8, 2017, the Company announced that Yanlin Wang, M.D., Ph.D., will join the Company as a scientific advisor for cannabinoid-based therapeutics targeting kidney diseases.

On March 22, 2017, the Company announced that Dr. Scott Friedman, M.D., will join the Company as a scientific advisor for cannabinoid-based therapeutics targeting liver diseases.

On March 29, 2017, the Company provided a corporate update on its Phase 2 clinical study of REV-004 (Bucillamine) in cystinuria and warrant exercise.

On April 12, 2017, the Company announced that its board of directors approved the grant of 965,000 incentive stock options to certain officers, directors, employees and consultants of the Company at an exercise price of \$0.28 per share expiring on April 10, 2027.

On May 30, 2017, the Company announced that it has entered into a sponsored research agreement with the University of Wisconsin-Madison to evaluate a novel drug delivery technology with a focus on cannabinoids for the potential to treat various diseases.

On June 7, 2017, the Company announced that it has obtained positive results from its research program of cannabinoid-based therapies targeting liver diseases, demonstrating certain cannabinoids being effective in a liver fibrosis model and may serve as novel treatments for liver fibrogenesis.



**REVIVE THERAPEUTICS LTD.**  
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**For the year ended June 30, 2017**  
**Dated – October 19, 2017**

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On August 15, 2017, the Company announced that Dr. Ram Subramanian, M.D., will join the Company as a Scientific Advisor for cannabinoid-based therapeutics targeting liver diseases.

On August 22, 2017, the Company announced that Dr. Arun Sanyal, MD, will join the Company as a Scientific Advisor for cannabinoid-based therapeutics targeting liver diseases.

On September 12, 2017, the Company announced the advancement of the research program with the University of Wisconsin-Madison to evaluate a novel drug delivery technology with a focus on cannabinoids for the potential to treat various diseases, such as pain and inflammation for the medical marijuana and pharmaceutical markets for Canada and the United States.

On September 19, 2017, the Company announced that it has entered into a license agreement with South Carolina Research Foundation ("SCRF"), under which Revive will acquire an exclusive license from SCRF to develop and commercialize a portfolio of patents based on cannabinoid-based therapeutics, such as cannabidiol, in the treatment of liver diseases.

On October 2, 2017, the Company announced that it has entered into a research collaboration with Sanyal Biotechnology LLC ("SanyalBio") focused on advancing cannabinoids for the potential treatment of liver diseases.

On October 11, 2017, the Company announced positive initial results from its research project with the University of Wisconsin Madison for the development of a novel cannabinoid delivery technology.

## **Outlook**

Pharmaceutical and biotechnology companies have commonly relied on two mainstream approaches to establish a product pipeline. The first being internal research and development efforts, which is expensive, time-consuming and involve a very high degree of risk. The second common approach is product in-licensing, which is limited by increased competition from well-established global pharmaceutical and biotechnology companies to in-license or acquire a limited number of interesting and high probability of success compounds. As such, there is a trend towards the drug repurposing development model to fill the pharmaceutical product pipeline gap.

Traditionally, once a compound in clinical development for a specific indication is deemed to lack effectiveness, yet have a good safety profile, the drug developer will stop the clinical development regardless if the compound could be effective in treating additional medical indications. Until now, any alternative or new uses were most often discovered by serendipity. The drug repurposing industry has gone beyond serendipity and new technologies such as bioinformatics-based approaches and high put screening approaches are being utilized by drug developers. Thus, the Company believes that the drug repurposing development model will become a core drug development strategy of pharmaceutical companies for many years to come.

The pharmaceutical industry is facing a number of significant pressures such as decreasing research and development productivity, increasing drug development costs, increasing patent protection loss of branded drugs, high regulatory barriers, evolving payer requirements, lower return on investment, generic drug competition and post-market clinical trial result failures due to safety concerns. Pharmaceutical companies are being forced to find more efficient and cost effective ways to improve their research and development strategies. There is increasing interest in drug repurposing to help fill this unmet drug development gap. Drug repurposing has the potential to fill the unmet need of pharmaceutical companies looking to fill their drug pipelines, provide a new source of revenue and increase return on investment. Drug repurposing is the process of developing new indications for existing drugs. Drug repurposing has a number of potential research and development advantages such as reduced time to market, reduced development cost, and the improved probability of success. Interestingly enough, the drug repurposing development model has

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not been fully adopted by pharmaceutical companies to address their new drug development needs. Revive aims to fill this gap for the pharmaceutical industry.

### Summary of Quarterly Results

The Company's quarterly information in the table below is prepared in accordance with IFRS.

| Three Months Ended | Total Revenue (\$) | Profit or Loss           |                                   | Total Assets (\$) |
|--------------------|--------------------|--------------------------|-----------------------------------|-------------------|
|                    |                    | Total (\$)               | Per Share (\$) <sup>(9)(10)</sup> |                   |
| June 30, 2017      | -                  | (534,476) <sup>(1)</sup> | (0.01)                            | 1,923,694         |
| March 31, 2017     | -                  | (452,707) <sup>(2)</sup> | (0.01)                            | 2,309,204         |
| December 31, 2016  | -                  | (271,013) <sup>(3)</sup> | (0.01)                            | 1,810,895         |
| September 30, 2016 | -                  | (357,704) <sup>(4)</sup> | (0.01)                            | 2,233,383         |
| June 30, 2016      | -                  | (516,547) <sup>(5)</sup> | (0.02)                            | 1,387,067         |
| March 31, 2016     | -                  | (496,671) <sup>(6)</sup> | (0.02)                            | 900,750           |
| December 31, 2015  | -                  | (811,915) <sup>(7)</sup> | (0.03)                            | 1,167,919         |
| September 30, 2015 | -                  | (912,799) <sup>(8)</sup> | (0.04)                            | 1,943,312         |

Notes:

- (1) Net loss of \$534,476 primarily consisted of \$69,679 research costs, \$67,146 professional fees and disbursements, \$146,148 salaries and benefits, \$129,970 stock-based compensation and \$33,543 consulting fees.
- (2) Net loss of \$452,707 primarily consisted of \$225,056 research costs, \$22,750 professional fees and disbursements, \$156,307 salaries and benefits, \$30,706 consulting fees and \$2,555 stock-based compensation.
- (3) Net loss of \$271,013 primarily consisted of \$56,369 research costs, \$44,330 professional fees and disbursements, \$143,610 salaries and benefits, \$93,193 consulting fees and \$5,877 stock-based compensation.
- (4) Net loss of \$357,704 primarily consisted of \$57,112 research costs, \$47,065 professional fees and disbursements, \$148,467 salaries and benefits, consulting fees of \$25,412 and \$5,877 stock-based compensation.
- (5) Net loss of \$516,547 primarily consisted of \$279,537 research costs, \$53,202 professional fees and disbursements, \$76,295 salaries and benefits, \$41,375 write-off of intangible assets and \$5,813 stock-based compensation.
- (6) Net loss of \$496,671 primarily consisted of \$2,940 consulting fees, \$247,721 research costs, \$62,354 professional fees and disbursements, \$112,688 salaries and benefits and \$22,574 stock-based compensation.
- (7) Net loss \$811,915 primarily consisted of \$50,000 consulting fees, \$387,298 research costs, \$35,945 professional fees and disbursements, \$113,491 salaries and benefits and \$43,487 stock-based compensation.
- (8) Net loss of \$912,799 primarily consisted of \$50,000 consulting fees, \$653,732 research costs, \$52,334 professional fees and disbursements, \$99,769 salaries and benefits and \$43,487 stock-based compensation.

- (9) Basic and diluted per share basis.
- (10) Per share amounts are rounded to the nearest cent, therefore aggregating quarterly amounts may not reconcile to year-to-date per share amounts.

## **Capital Management**

The Company manages its capital with the following objectives:

- to ensure sufficient financial flexibility to achieve the ongoing business objectives including funding of future growth opportunities, and pursuit of acquisitions; and
- to maximize shareholder return.

The Company monitors its capital structure and makes adjustments according to market conditions in an effort to meet its objectives given the current outlook of the business and industry in general. The Company may manage its capital structure by issuing new shares, repurchasing outstanding shares, adjusting capital spending, or disposing of assets. The capital structure is reviewed by management and the board of directors on an ongoing basis.

The Company considers its capital to be total shareholders' equity, comprising share capital, warrants and broker warrants, stock options and accumulated deficit which at June 30, 2017, totalled \$1,615,192 (June 30, 2016 - \$568,637).

The Company manages capital through its financial and operational forecasting processes. The Company reviews its working capital and forecasts its future cash flows based on operating expenditures, and other investing and financing activities. The forecast is updated based on activities related to its research programs. Information is provided to the Board of Directors of the Company. The Company's capital management objectives, policies and processes have remained unchanged during the year ended June 30, 2017.

The Company is not subject to any capital requirements imposed by a lending institution or regulatory body, other than Policy 2.5 of the Exchange which requires adequate working capital or financial resources of the greater of (i) \$50,000 and (ii) an amount required in order to maintain operations and cover general and administrative expenses for a period of 6 months. As of June 30, 2017, management believes it is compliant with known requirements. The Company expects that its capital resources will be sufficient to discharge its liabilities as of the current statement of financial position date.

## **Off-Balance-Sheet Arrangements**

As of the date of this MD&A, the Company does not have any off-balance-sheet arrangements that have, or are reasonably likely to have, a current or future effect on the results of operations or financial condition of the Company, including, and without limitation, such considerations as liquidity and capital resources.

## **Proposed Transactions**

As of the date of this MD&A, no proposed transaction has been approved by the Board of Directors.

## **Selected Annual Financial Information**

The following is selected financial data derived from the audited consolidated financial statements of the Company at June 30, 2017, 2016 and 2015.

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|  | <b>Year ended<br/>June 30, 2017</b> | <b>Year ended<br/>June 30, 2016</b> | <b>Year ended<br/>June 30, 2015</b> |
|--|-------------------------------------|-------------------------------------|-------------------------------------|
| Net loss                               | \$(1,615,900)                       | \$(2,737,932)                       | \$(2,031,102)                       |
| Net loss per share (basic and diluted) | \$(0.03)                            | \$(0.11)                            | \$(0.09)                            |
|  | <b>As at June 30,<br/>2017</b>      | <b>As at June 30,<br/>2016</b>      | <b>As at June 30,<br/>2015</b>      |
| Total assets                           | \$1,923,694                         | \$1,387,067                         | \$2,666,426                         |

- The net loss for the year ended June 30, 2017, consisted primarily of (i) research costs of \$408,216; (ii) salaries and benefits of \$594,532; (iii) stock-based compensation of \$144,279; (iv) consulting fees of \$182,854; (v) professional fees of \$181,291 and office expense of \$127,562;
- The net loss for the year ended June 30, 2016, consisted primarily of (i) research costs of \$1,568,288; (ii) salaries and benefits of \$402,243; (iii) stock-based compensation of \$115,361; (iv) consulting fees of \$102,940; (v) office expenses of \$267,106 and (vi) professional fees of \$203,835;
- The net loss for the year ended June 30, 2015, consisted primarily of (i) research costs of \$747,559; (ii) salaries and benefits of \$295,328; (iii) stock-based compensation of \$293,603; (iv) consulting fees of \$222,692; (v) office expenses of \$234,888 and (vi) professional fees of \$187,141;

## **Discussion of Operations**

### Twelve months ended June 30, 2017, compared to the twelve months ended June 30, 2016

The Company's net loss totalled \$1,615,900 for the twelve months ended June 30, 2017, with basic and diluted loss per share of \$0.03. This compares with a net loss of \$2,737,932 with basic and diluted loss per share of \$0.11 for the twelve months ended June 30, 2016.

Net loss for twelve months ended June 30, 2017, principally related to research costs of \$408,216, professional fees and disbursements of \$181,291, stock-based compensation of \$144,279, salaries and benefits of \$594,532, consulting fees of \$182,854, depreciation and amortization of \$3,572, rent of \$33,271, and office expenses of \$127,562. Net loss for twelve months ended June 30, 2016 principally related to research costs of \$1,568,288, professional fees and disbursements of \$203,835, stock-based compensation of \$115,361, salaries and benefits of \$402,243, consulting fees of \$102,940, write-off of intangible assets of \$41,375, depreciation and amortization of \$6,224, rent of \$30,560, and office expenses of \$267,106.

Variations in research costs are discussed on a program-by-program basis above under "Description of Business".

*Three months ended June 30, 2017, compared to the three months ended June 30, 2016*

The Company's net loss totalled \$534,476 for the three months ended June 30, 2017, with basic and diluted loss per share of \$0.01. This compares with a net loss of \$516,547 with basic and diluted loss per share of \$0.02 for the three months ended June 30, 2016.

Net loss for three months ended June 30, 2017, principally related to research costs of \$69,679, professional fees and disbursements of \$67,146, stock-based compensation of \$129,970, salaries and benefits of \$146,148, consulting fees of \$33,543, depreciation and amortization of \$893, rent of \$8,402, and office expenses of \$138,372. Net loss for three months ended June 30, 2016 principally related to research costs of \$279,537, professional fees and disbursements of \$53,202, stock-based compensation of \$5,813, salaries and benefits of \$76,295, write-off of intangible assets of \$41,375, depreciation and amortization of \$1,557, rent of \$7,559, and office expenses of \$51,209.

Variations in research costs are discussed on a program-by-program basis above under "Description of Business".

### **Liquidity and Financial Position**

Cash and cash equivalents used in operating activities was \$2,801,224 for the year ended June 30, 2017. Operating activities were affected by a \$3,572 adjustment for depreciation and amortization, \$144,279 stock-based compensation, \$8,415 write-off of intangible assets, \$68,092 gain on settlement of accounts payable and the net change in non-cash working capital balances of \$553,498 because of increases in other receivables, increase in prepaid expenses and decrease in accounts payable and accrued liabilities.

Cash and cash equivalents used in investing activities was \$1,515 for the year ended June 30, 2017. This pertained to the purchase of intangible assets.

Cash and cash equivalents provided by financing activities was \$2,518,176 for the year ended June 30, 2017, which represents proceeds from the issuance of shares and warrants and proceeds from exercise of warrants.

At June 30, 2017, Revive had \$1,768,676 in cash and cash equivalents.

Accounts payable and accrued liabilities were \$308,502 at June 30, 2017. The Company's cash and cash equivalents balance as at June 30, 2017 is sufficient to pay these liabilities.

The Company has no operating revenues and therefore must utilize its income from financing transactions to maintain its capacity to meet ongoing operating activities.

As of June 30, 2017, and to the date of this MD&A, the cash resources of Revive are held with one Canadian chartered bank. The Company has no debt and its credit and interest rate risk is minimal. Accounts payable and accrued liabilities are short-term and non-interest-bearing.

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As of June 30, 2017, based on current projections, Revive's working capital of \$1,588,832 is not sufficient to meet its planned development activities for the financial year ending June 30, 2018. The table below outlines the Company's planned uses of working capital:

| <b>Use of Capital <sup>(1)</sup></b>                    | <b>Estimated Cost</b> | <b>Spent to date (approx.)</b> | <b>Remaining Funds to Spend or (excess)</b> |
|---|-----------------------|--------------------------------|---|
| REV-002 research development, clinical trials           | \$100,000             | \$51,000                       | \$49,000                                    |
| REV-004 research development, clinical trials           | \$980,000             | \$264,000                      | \$716,000                                   |
| General research and development <sup>(4)</sup>         | \$350,000             | \$178,000                      | \$172,000                                   |
| Intellectual Property Costs                             | \$50,000              | \$nil                          | \$50,000                                    |
| General & Administrative for fiscal 2018 <sup>(2)</sup> | \$1,092,000           | \$nil                          | \$1,092,000                                 |
| Settlement of lawsuit <sup>(3)</sup>                    | undetermined          | undetermined                   | undetermined                                |
| <b>Total</b>  | <b>\$2,572,000</b>    | <b>\$493,000</b>               | <b>\$2,079,000</b>                          |

Notes:

- (1) The use of proceeds provided in the table above should be considered estimates. Actual expenditures to satisfy these estimated costs may, and most likely will, differ from these estimates.
- (2) General and Administrative expenses estimated for the year ended June 30, 2018, is as follows:  
Salaries and benefits (\$600,000), consulting fees (\$150,000), office lease (\$30,000), travel (\$30,000), insurance (\$45,000), professional fees (\$150,000), transfer agent and regulatory fees (\$37,000), technology expenses (\$20,000) and marketing (\$30,000).
- (3) Settlement amount for lawsuit is undetermined as of the date of this MD&A. See "Commitments and Contingency" below.
- (4) Estimated general research costs, which also includes cannabinoids and drug delivery programs.

The Company believes that it has insufficient cash on hand to fund its planned expenditures for the financial year ended ending June 30, 2018. Further financings will be required to develop the Company's product pipeline, to meet ongoing obligations and discharge its liabilities in the normal course of business. There is some flexibility in terms of the pace and timing of product pipeline costs and how expenditures have been, or may be adjusted, limited or deferred subject to current capital resources and the potential to raise further funds. The Company will continue to manage its expenditures essential to the viability of its product pipeline. There is no assurance that additional funds can be raised upon terms acceptable to the Company or at all and funding for small companies remains challenging. Accordingly, the Company's consolidated financial statements have been prepared on a going concern basis. Material adjustments could be required if the Company cannot obtain adequate financing. See "Risk Factors".

### **Related Party Transactions**

Related parties include the directors, close family members and enterprises that are controlled by these individuals as well as certain persons performing similar functions.

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(a) Revive engaged in the following transactions with related parties:

| Names   | Year Ended<br>June 30,<br>2017<br>(\$) | Year Ended<br>June 30,<br>2016<br>(\$) |
|---|--|--|
| Marrelli Support Services Inc. ("Marrelli Support") (i) | 48,172                                 | 44,290                                 |
| DSA Corporate Services ("DSA") (ii)                     | 21,730                                 | 20,892                                 |
| RangerCap Inc. ("RangerCap") (iii)                      | nil                                    | 100,000                                |
| <b>Total</b>  | <b>69,902</b>                          | <b>165,182</b>                         |

(i) Marrelli Support was owed \$2,511 as at June 30, 2017, (June 30, 2016 - \$2,683) for the services of Carmelo Marrelli to act as Chief Financial Officer ("CFO") of the Company. This amount was included in accounts payable and accrued liabilities. The Company has entered into a consulting agreement (the "Marrelli Consulting Agreement") with Marrelli Support and Mr. Marrelli to provide the services of Mr. Marrelli as CFO of the Company. The term of the Marrelli Consulting Agreement commenced on January 8, 2013, and shall continue until terminated by either Mr. Marrelli or the Company. Pursuant to the Marrelli Consulting Agreement, Mr. Marrelli is entitled to receive monthly compensation of \$1,250 per month, and incentive stock option grants on a reasonable basis, consistent with the grant of options to other grantees. In addition, Marrelli Support provides bookkeeping services to the Company. Mr. Marrelli is the President of Marrelli Support. The amounts charged by Marrelli Support are based on what Marrelli Support usually charges its clients. The Company expects to continue to use Marrelli Support for an indefinite period of time.

(ii) DSA was owed \$2,225 as at June 30, 2017, (June 30, 2016 - \$4,727) for corporate secretarial and filing services. This amount was included in accounts payable and accrued liabilities. DSA is a private company controlled by Carmelo Marrelli, the CFO of the Company. Carmelo Marrelli is also the corporate secretary and sole director of DSA. Services were incurred in the normal course of operations for corporate secretarial, electronic filing and news dissemination services. The Company expects to continue to use DSA's services for an indefinite period of time.

(iii) RangerCap is owned by Craig Leon, Chief Executive Officer ("CEO") and one of the directors of the Company. The Company has entered into a consulting agreement (the "RangerCap Consulting Agreement") with RangerCap and Mr. Leon to provide the services of Mr. Leon as consultant of the Company. The term of the RangerCap Consulting Agreement commenced on January 1, 2015, and expired on December 31, 2015. Pursuant to the RangerCap Consulting Agreement, Mr. Leon was entitled to receive monthly compensation of \$16,667 per month. In addition, Mr. Leon provided guidance and advice regarding general business, product development and capital markets strategy to the Company.



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(b) Remuneration of directors and key management personnel of the Company, excluding consulting fees, was as follows:

| <b>Stock-based Compensation</b>             | <b>Year Ended<br/>June 30,<br/>2017<br/>(\$)</b> | <b>Year Ended<br/>June 30,<br/>2016<br/>(\$)</b> |
|---|--|--|
| <b>Names</b>                                |  |  |
| Craig Leon, CEO and Director                | 20,203   | 17,247   |
| Bill Jackson, Director                      | 20,203   | 17,247   |
| Carlo Sansalone, Director                   | 13,468   | 11,497   |
| Fabio Chianelli, President and Director     | 13,468   | 11,497   |
| Carmelo Marrelli, CFO                       | 5,387  | 2,300  |
| Dr. Bev Incledon, VP Research & Development | 3,368  | 1,151  |
| <b>Total</b>                                | <b>76,097</b>                                    | <b>60,939</b>                                    |

| <b>Salaries and Benefits</b> | <b>Year Ended<br/>June 30,<br/>2017<br/>(\$)</b> | <b>Year Ended<br/>June 30,<br/>2016<br/>(\$)</b> |
|------------------------------|--|--|
| <b>Names</b>                 |  |  |
| Craig Leon, CEO and Director | 250,000  | nil  |
| Fabio Chianelli, President   | 250,000  | 259,615  |
| <b>Total</b>                 | <b>500,000</b>                                   | <b>259,615</b>                                   |

(c) Major shareholders:

As at June 30, 2017, no person or corporation beneficially owns or exercises control or direction over common shares of the Company carrying more than 10% of the voting rights attached to all of the common shares of the Company other than Mr. Fabio Chianelli, the President and a Director of the Company, who owns or controls, directly or indirectly, 12.95% of the issued and outstanding shares of the Company. These stockholdings can change at any time at the discretion of the owner.

None of the Company's major shareholders have different voting rights other than holders of the Company's common shares.

The Company is not aware of any arrangements, the operation of which may at a subsequent date result in a change in control of the Company. Other than Mr. Fabio Chianelli, the President and a Director of the Company, who owns or controls, directly or indirectly, 12.95% of the issued and outstanding shares of the Company on a partially diluted basis, the Company is not directly or indirectly owned or controlled by another corporation, by any government or by any natural or legal person severally or jointly.

## **Change in Accounting Policies**

### **Recent accounting pronouncements**

IFRS 9 - Financial Instruments ("IFRS 9") was issued by the IASB on November 12, 2009 and then issued in its final form on July 24, 2014 and will replace IAS 39 - Financial Instruments: Recognition and Measurement ("IAS 39"). IFRS 9 replaces the multiple rules in IAS 39 with a single approach to determine whether a financial asset is measured at amortized cost or fair value and a new mixed measurement model for debt instruments having only two categories: amortized cost and fair value. The approach in IFRS 9 is based on how an entity manages its financial instruments in the context of its business model and the

contractual cash flow characteristics of the financial assets. The new standard also requires a single impairment method to be used, replacing the multiple impairment methods in IAS 39. IFRS 9 is effective for annual periods beginning on or after January 1, 2018. The Company is in the process of assessing the impact of this pronouncement.

IFRS 16, Leases ("IFRS 16") was issued on January 13, 2016. The new standard is effective for annual periods beginning on or after January 1, 2019. Earlier application is permitted for entities that apply IFRS 15, "Revenue from contracts with customers" at or before the date of initial adoption of IFRS 16. IFRS 16 will replace IAS 17, "Leases". This standard introduces a single lessee accounting model and requires a lessee to recognize assets and liabilities for all leases with a term of more than 12 months, unless the underlying asset is of low value. A lessee is required to recognize a right-of-use asset representing its right to use the underlying asset and a lease liability representing its obligation to make lease payments. This standard substantially carries forward the lessor accounting requirements of IAS 17, while requiring enhanced disclosures to be provided by lessors. Other areas of the lease accounting model have been impacted, including the definition of a lease. Transitional provisions have been provided. The Company is in the process of assessing the impact of this pronouncement.

## **Share Capital**

Other than as described below, as of the date of this MD&A, there are no equity or voting securities of the Company outstanding, and no securities convertible into, or exercisable or exchangeable for, voting or equity securities of the Company.

As of the date of this MD&A, the outstanding capital of the Company includes (i) 53,893,567 common shares of the Company issued and outstanding; (ii) Warrants exercisable for the purchase of 5,655,315 common shares; (iii) Broker Warrants exercisable for the purchase of 197,750 Units with each Unit composed of one common share of the Company and one Warrant, with an aggregate total of 395,500 common shares issuable upon full exercise of the Units and the underlying Warrants; and (iv) stock options exercisable for the purchase of 2,518,151 common shares.

## **Financial Instruments**

The Company's activities expose it to a variety of financial risks: credit risk, liquidity risk and market risk (including interest rate, foreign exchange rate, and price risk).

Risk management is carried out by the Company's management team with guidance from the Board of Directors. The Board of Directors also provides regular guidance for overall risk management.

### **Credit risk**

Credit risk is the risk of loss associated with a counterparty's inability to fulfill its payment obligations. The Company's credit risk is primarily attributable to cash and other receivables. Cash is held with select major Canadian chartered banks, from which management believes the risk of loss to be minimal.

Other receivables include sales tax recoverable from government authorities in Canada, which are in good standing as of June 30, 2017. Management believes that the credit risk concentration with respect to financial instruments included in sales tax recoverable is minimal.

### **Liquidity risk**

Liquidity risk is the risk that the Company will not have sufficient cash resources to meet its financial obligations as they come due. The Company's liquidity and operating results may be adversely affected if the Company's access to the capital market is hindered, whether as a result of a downturn in stock market conditions generally or related to matters specific to the Company. The Company generates cash flow

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primarily from its financing activities. As at June 30, 2017, the Company had a cash and cash equivalents balance of \$1,768,676 (June 30, 2016 - \$1,333,239) to settle current liabilities of \$308,502 (June 30, 2016 - \$818,430). The Company regularly evaluates its cash position to ensure preservation and security of capital as well as maintenance of liquidity.

**Market risk**

(a) Interest rate risk

The Company has cash balances. The Company's current policy is to invest excess cash held as collateral in guaranteed investment certificates or interest bearing accounts of select major Canadian chartered banks. The Company regularly monitors its cash activities in compliance with its cash management policy.

The Company is exposed to the risk that the value of financial instruments will change due to movements in market interest rates. As of June 30, 2017, the Company's interest rate risk mainly relates to cash balances. Sensitivity to a plus or minus 1% change in interest rates would affect the reported comprehensive loss by approximately \$18,000.

(b) Foreign currency risk

The Company's functional and reporting currency is the Canadian dollar and major purchases are transacted in Canadian dollars. As of June 30, 2017, sensitivity to a plus or minus 10% change in US dollar foreign exchange rate would affect the reported comprehensive loss by approximately \$15,000.

**Fair value hierarchy and liquidity risk disclosure**

Cash and cash equivalents are considered Level 1 with the fair value hierarchy as at June 30, 2017.

**Commitments and Contingency**

Commitments

The Company has entered into an agreement (the "President Agreement") with an officer (Fabio Chianelli) (the "Officer") of the Company to provide services to the Company in the general capacity of President and to undertake the duties and exercise the powers associated with this role. Under the terms of the President Agreement, the President is contracted by the Company for an indefinite term, commencing as of January 1, 2014. The Company shall pay the President a \$250,000 base salary per annum (the "Annual Base Salary") and annual bonus payments (the "Bonus") from time to time, at the Board's entire discretion, of up to 100% of the Annual Base Salary based on the achievement of corporate goals and benchmarks relating to the Company's overall performance. The President Agreement requires an additional contingent lump-sum payment equal to the Officer's then Annual Base Salary and the Bonus paid or declared to the Officer, if any, in the Company's previously completed fiscal year upon the occurrence of a change of control or termination without cause. As a triggering event has not taken place, the contingent payments have not been reflected in the year ended June 30, 2017, financial statements.

The Company has entered into an agreement (the "CEO Agreement") with an officer (Craig Leon) (the "Employee") of the Company to provide services to the Company in the general capacity of CEO and to undertake the duties and exercise the powers associated with this role. Under the terms of the CEO Agreement, the CEO is contracted by the Company for an indefinite term, commencing as of July 1, 2016. The Company shall pay the CEO a \$250,000 base salary per annum (the "Yearly Base Salary") and annual bonus payments (the "Bonus Payment") from time to time, at the Board's entire discretion, of up to 100% of the Yearly Base Salary based on the achievement of corporate goals and benchmarks relating to the Company's overall performance. The CEO Agreement requires an additional contingent lump-sum payment

equal to the Employee's then Yearly Base Salary and the Bonus Payment paid or declared to the Employee, if any, in the Company's previously completed fiscal year upon the occurrence of a change of control or termination without cause. As a triggering event has not taken place, the contingent payments have not been reflected in the year ended June 30, 2017, financial statements.

In March 2015, the Company entered a new lease agreement commencing on September 2015 for a 12-month period. In August 2016, the Company entered a new lease agreement commencing on September 1, 2016 for a 12-month period. The Company is required to pay minimum annual lease payment of \$16,073. In August 2017, the Company entered a new lease agreement commencing on September 2017 for a 24-month period. The Company is required to pay minimum annual lease payment of \$15,468.

#### Contingency

The Company is in dispute with a supplier over invoices in the amount of \$827,574 plus interest for which the supplier has sought arbitration. The dispute is in arbitration. No provision has been set up in the accounts of the Company. Any settlement and/or payment will be accounted for in the year it occurs. Readers are cautioned that the eventual resolution of this liability will be based on additional information and the occurrence of future events.

### **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 MD&A. 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 factors.

#### **History of Operating Losses**

To date, Revive has not recorded any revenues from the sale of diagnostic or therapeutic products. Since incorporation, Revive has accumulated net losses and expects such losses to continue as it commences product and clinical development and eventually enters into license agreements for its technology. Management expects to continue to incur substantial operating losses unless and until such time as product sales generate sufficient revenues to fund continuing operations.

#### **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 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 its business and results of operations.

### **Unproven Market**

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.

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

The Company has no, and does not expect to have any, in-house manufacturing, pharmaceutical 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 the Company's product being developed by the Company may be large and will require substantial sales and marketing capability. At the present time, Revive does not have any internal capability to market pharmaceutical products. The Company intends to enter into one or more strategic partnerships or collaborative arrangements with pharmaceutical 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; 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 operation of the Company.

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

Pre-clinical studies and Phase I and Phase II clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in pre-clinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. Favourable results in early trials may not be repeated in later trials. A number of companies in the life sciences industry have suffered significant setbacks in advanced clinical trials, even after positive results in earlier trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminate. Any pre-clinical data and the clinical results obtained for our technologies may not predict results from studies in larger numbers of subjects drawn from more diverse populations or in the commercial setting, and also may not predict the ability of our products to achieve their intended goals, or to do so safely.

#### **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 pharmaceutical products 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.

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

The Company will need additional capital to complete its current research and development programs. It is anticipated that future research, additional pre-clinical and toxicology studies and manufacturing 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 technologies with the possible loss of license rights to these technologies.

#### **Competition**

The market for Revive's technology is highly competitive. The Company will compete with other research teams who are also examining potential therapeutics with regards to respiratory and breathing disorders, gout, rare diseases, cognitive dysfunction, and central nervous system disorders. Many of its competitors have greater financial and operational resources and more experience in research and development than the Company will. These and other companies may have developed or could in the future develop new technologies that compete with the Company's technologies or even render its technologies obsolete.

Competition in Revive's markets is primarily driven by (i) timing of technological introductions, (ii) ability to develop, maintain and protect proprietary products and technologies, and (iii) expertise of research and development team.



### **Intellectual Property**

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

### **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.

### **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.

### **Lack of Supporting Clinical Data**

The clinical effectiveness and safety of any of Revive's current or future products is not yet supported by clinical data and the medical community has not yet developed a large body of peer reviewed literature that supports the safety and efficacy of the Revive's products. If future studies call into question the safety or



efficacy of the Revive's products, the Revive's business, financial condition or results of operations could be adversely affected.

### **Research and Development Risk**

A principal component of the Revive's business strategy is to expand its product offering to fully exploit the core technologies that have been assigned a patent application from Xenexus Pharmaceuticals Pty Ltd. As such, Revive's organic growth and long-term success is primarily dependent on its ability to successfully develop new and current products and it will likely incur significant research and development expenditures. Revive cannot be certain that any investment in research and development will yield technically feasible or commercially viable products. Furthermore, its ability to discover and develop products will depend on its ability to:

- retain key scientists as employees or partners;
- identify high quality therapeutic targets;
- identify potential drug candidates;
- develop products internally;
- successfully complete laboratory testing and clinical trials on humans;
- obtain and maintain necessary intellectual property rights to the Revive's products;
- obtain and maintain necessary United States and other regulatory approvals for conducting clinical trials;
- obtain and maintain necessary United States and other regulatory approvals for its products; collaborate with third parties to assist in the development of its products; and
- enter into arrangements with third parties to co-develop, license, and commercialize its products.

Revive may not be successful in discovering and developing drug products. Failure to so introduce and advance new and current products could materially and adversely affect the Revive's operations and financial condition.

### **Pre-Clinical and Clinical Development Risks**

Revive must demonstrate the safety and efficacy of REV-002, REV-004, REV-005, REV-100, REV-200, and REV-201 (collectively, the "Current Candidates") (and any other products it develops) through, among other things, extensive pre-clinical and clinical testing. The Company's research and development programs are at an early stage of development. Numerous unforeseen events during, or as a result of, the testing process could delay or prevent commercialization of any products the Company develops, including (i) the results of pre-clinical and clinical studies may be inconclusive, may demonstrate potentially unsafe drug characteristics, or may not be indicative of results that will be obtained in human clinical trials, and (ii) the safety and efficacy results attained in the pre-clinical and clinical studies may not be indicative of results that are obtained in later clinical trials; and after reviewing pre-clinical and clinical study results, the Company or its partners or collaborators may abandon projects that were previously thought to be promising.

Pre-clinical and clinical studies are very expensive, can run into unexpected difficulties and the outcomes are uncertain. Revive's Phase II-A proof of concept study for REV-002 has been completed and close-out procedures are expected to be completed by June 2018. Revive's Phase II-A proof of concept study for REV-004 is expected to be completed by December 2017. The data collected from the Revive's pre-clinical and clinical studies for the Current Candidates (or any other products Revive develops) may not be sufficient to support the regulatory approval of human testing of such product(s). Pre-clinical and clinical studies of Revive's products may not be completed on schedule or on budget. Revive's failure to complete its pre-clinical and clinical studies on schedule or on budget, or its failure to adequately demonstrate the

safety and efficacy of any of the products it develops, could delay or prevent regulatory approval of such products, which could adversely affect Revive's business, financial condition or results of operations.

#### **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 development industry in general and Revive in particular than would be the case if the business was more diversified. Currently, Revive's primary focus is the development of REV-004 and the advancement of its cannabinoid-based therapeutic programs. Accordingly, Revive is dependent on its ability to develop and commercialize REV-004 and its cannabinoid-based therapeutic programs, 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.

#### **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.

#### **Regulatory Risk**

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 Canada 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.

### **International Operations**

Revive's international operations expose it and its representatives, agents and distributors to risks inherent to operating in foreign jurisdictions which could materially adversely affect its operations and financial position. These risks include (i) country-specific taxation policies, (ii) imposition of additional foreign governmental controls or regulations, (iii) export license requirements, (iv) changes in tariffs and other trade restrictions, and (v) complexity of collecting receivables in a foreign jurisdiction.

Moreover, applicable agreements relating to business in foreign jurisdictions are governed by foreign laws and are subject to dispute resolution in the courts of, or through arbitration proceedings in, the country or region in which the parties are located or another jurisdiction agreed upon by the parties. Revive cannot accurately predict whether such forum will provide an effective and efficient means of resolving disputes that may arise in the future. Even if it obtains a satisfactory decision through arbitration or a court proceeding, Revive could have difficulty in enforcing any award or judgment on a timely basis or at all.

### **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.

### **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.

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

The Company may issue additional shares in the future, which may dilute a shareholder's holdings in the Company. The Company's articles permit the issuance of an unlimited number of the Company's shares and an unlimited number of preferred shares, issuable in series, and the shareholders of the Company will have no pre-emptive rights in connection with such further issuances. The board of directors of the Company has the discretion to determine the provisions attaching to any series of preferred shares and the price and the terms of issue of further issuances of Company's shares.

### **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.

## **Disclosure of Internal Controls**

Management has established processes to provide them with sufficient knowledge to support representations that they have exercised reasonable diligence to ensure that (i) the consolidated financial statements do not contain any untrue statement of material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it is made, as of the date of and for the periods presented by the consolidated financial statements, and (ii) the consolidated financial statements fairly present in all material respects the financial condition, results of operations and cash flow of the Company, as of the date of and for the periods presented.

In contrast to the certificate required for non-venture issuers under National Instrument 52-109, Certification of Disclosure in Issuers' Annual and Interim Filings ("NI 52-109"), the Venture Issuer Basic Certificate does not include representations relating to the establishment and maintenance of disclosure controls and procedures ("DC&P") and internal control over financial reporting ("ICFR"), as defined in NI 52-109. In particular, the certifying officers filing this certificate are not making any representations relating to the establishment and maintenance of:

(i) controls and other procedures designed to provide reasonable assurance that information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and

(ii) a process to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with the issuer's GAAP (IFRS).

The issuer's certifying officers are responsible for ensuring that processes are in place to provide them with sufficient knowledge to support the representations they are making in the certificate. Investors should be aware that inherent limitations on the ability of certifying officers of a venture issuer to design and implement on a cost effective basis DC&P and ICFR as defined in NI 52-109 may result in additional risks to the quality, reliability, transparency and timeliness of interim and annual filings and other reports provided under securities legislation.

## **Additional Disclosure for Venture Issuers Without Significant Revenue**

### **Office expenses**

|                          | <b>Year Ended<br/>June 30, 2017<br/>(\$)</b> | <b>Year Ended<br/>June 30, 2016<br/>(\$)</b> |
|--------------------------|--|--|
| Reporting issuer costs   | 54,107                                       | 195,191                                      |
| Administrative           | 18,379                                       | 2,677  |
| Travel and accommodation | 10,936                                       | 18,258                                       |
| Insurance                | 36,142                                       | 45,590                                       |
| Meals and entertainment  | 6,177  | 6,439  |
| Bank charges             | 4,949  | 6,860  |
| Interest income          | (3,128)                                      | (7,909)                                      |
| <b>Total</b>             | <b>127,562</b>                               | <b>267,106</b>                               |

**REVIVE THERAPEUTICS LTD.**  
**Management's Discussion & Analysis**  
**For the year ended June 30, 2017**  
**Dated – October 19, 2017**

**Intangible assets**

| <b>Cost</b>                   | <b>REV-001</b>  | <b>REV-002</b>  | <b>REV-003</b> | <b>Total</b>    |
|-------------------------------|-----------------|-----------------|----------------|-----------------|
|                               |                 |                 |                |                 |
| <b>Balance, June 30, 2015</b> | <b>\$48,052</b> | <b>\$25,000</b> | <b>\$9,897</b> | <b>\$82,949</b> |
| Write-off                     | (48,052)        | nil             | nil            | (48,052)        |
| <b>Balance, June 30, 2016</b> | <b>\$nil</b>    | <b>\$25,000</b> | <b>\$9,897</b> | <b>\$34,897</b> |
| Additions                     | nil             | 1,515           | nil            | 1,515           |
| Write-off                     | nil             | nil             | (9,897)        | (9,897)         |
| <b>Balance, June 30, 2017</b> | <b>\$nil</b>    | <b>\$26,515</b> | <b>\$nil</b>   | <b>\$26,515</b> |

| <b>Accumulated amortization</b> | <b>REV-001</b> | <b>REV-002</b> | <b>REV-003</b> | <b>Total</b>   |
|---------------------------------|----------------|----------------|----------------|----------------|
|                                 |                |                |                |                |
| <b>Balance, June 30, 2015</b>   | <b>\$4,274</b> | <b>\$3,280</b> | <b>\$492</b>   | <b>\$8,046</b> |
| Amortization for the year       | 2,403          | 1,250          | 495            | 4,148          |
| Write-off                       | (6,677)        | nil            | nil            | (6,677)        |
| <b>Balance, June 30, 2016</b>   | <b>\$nil</b>   | <b>\$4,530</b> | <b>\$987</b>   | <b>\$5,517</b> |
| Amortization for the year       | nil            | 1,288          | 495            | 1,783          |
| Write-off                       | nil            | nil            | (1,482)        | (1,482)        |
| <b>Balance, June 30, 2017</b>   | <b>\$nil</b>   | <b>\$5,818</b> | <b>\$nil</b>   | <b>\$5,818</b> |

**Research and development**

|              | <b>Year Ended<br/>June 30, 2017<br/>(\$)</b> | <b>Year Ended<br/>June 30, 2016<br/>(\$)</b> |
|--------------|--|--|
| REV-001      | nil  | nil  |
| REV-002      | 50,983                                       | 1,516,950                                    |
| REV-003      | nil  | nil  |
| REV-004      | 264,419                                      | 42,954                                       |
| REV-005      | nil  | 1,702  |
| Cannabinoids | 92,814                                       | nil  |
| Other        | nil  | 6,682  |
| <b>Total</b> | <b>408,216</b>                               | <b>1,568,288</b>                             |

The Company is no longer pursuing development of REV-001 (respiratory depression), REV-003 (Rett syndrome) and REV-005 (Wilson disease). The Company will focus on the Phase 2 clinical study of REV-004 (Cystinuria) and the research and development of its cannabinoids-based therapeutics programs in pain, inflammation, and liver diseases. In addition, the Company will continue to seek partnership opportunities for its product development programs.