

**OFFERING DOCUMENT  
UNDER THE LISTED ISSUER FINANCING EXEMPTION**

NOVEMBER 30, 2022



**REVIVE THERAPEUTICS LTD.**

(the “Company”)

**WHAT ARE WE OFFERING?**

- Offering:** A minimum of 20,000,000 units and a maximum of 33,333,333 units at a price of \$0.15 (the “Units”). Each Unit consists of one (1) common share of the Company (a “Unit Share”) and one (1) Common Share purchase warrant (a “Warrant”). Each Warrant is exercisable into one Common Share at a price of \$0.20 (a “Warrant Share”) for a period of 36 months (the “Offering”).
- Offering Price:** \$0.15 per Unit
- Offering Amount:** A minimum of 20,000,000 Units and a maximum of 33,333,333 Units, for minimum gross proceeds of \$3,000,000 and maximum gross proceeds of \$5,000,000.
- Closing Date:** On or about December 14, 2022
- Exchange:** The Common Shares of the Company are listed on the Canadian Securities Exchange (“CSE”) under the trading symbol “RVV” and on the OTCQB Venture Market (“OTCQB”) under the trading symbol “RVVTF”.
- Last Closing Price:** On November 29, 2022, the closing price of the Common Shares on the CSE and OTCQB was \$0.18 and US \$0.13, respectively.

*No securities regulatory authority or regulator has assessed the merits of these securities or reviewed this document. Any representation to the contrary is an offence. This offering may not be suitable for you and you should only invest in it if you are willing to risk the loss of your entire investment. In making this investment decision, you should seek the advice of a registered dealer.*

**The Company is conducting a listed issuer financing under section 5A.2 of National Instrument 45-106 Prospectus Exemptions. In connection with this Offering, the Company represents the following is true:**

- The issuer has active operations and its principal asset is not cash, cash equivalents or its exchange listing.
- The issuer has filed all periodic and timely disclosure documents that it is required to have filed.
- The total dollar amount of this offering, in combination with the dollar amount of all other offerings made under the listed issuer financing exemption in the 12 months immediately before the date of this offering document, will not exceed \$5,000,000.

- **The issuer will not close this offering unless the issuer reasonably believes it has raised sufficient funds to meet its business objectives and liquidity requirements for a period of 12 months following the distribution.**
- **The issuer will not allocate the available funds from this offering to an acquisition that is a significant acquisition or restructuring transaction under securities law or to any other transaction for which the issuer seeks security holder approval.**

## **CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION**

This offering document contains “forward-looking information” within the meaning of applicable Canadian and United States securities laws, which is based upon the Company’s current internal expectations, estimates, projections, assumptions and beliefs. The forward-looking information included in this offering document are made only as of the date of this offering document. Such forward-looking statements and forward-looking information include, but are not limited to, statements concerning future exploration plans at the Company’s mineral properties, including exploration timelines and anticipated costs; completion of the Offering, the Company’s expectations with respect to the use of proceeds and the use of the available funds following completion of the Offering; raising the minimum or maximum proceeds of the Offering; and completion of the Offering and the date of such completion. Forward-looking statements or forward-looking information relate to future events and future performance and include statements regarding the expectations and beliefs of management based on information currently available to the Company. Such forward-looking statements and forward-looking information often, but not always, can be identified by the use of words such as “plans”, “expects”, “potential”, “is expected”, “anticipated”, “is targeted”, “budget”, “scheduled”, “estimates”, “forecasts”, “intends”, “anticipates”, or “believes” or the negatives thereof or variations of such words and phrases or statements that certain actions, events or results “may”, “could”, “would”, “might” or “will” be taken, occur or be achieved.

Forward-looking statements or forward-looking information are subject to a variety of risks and uncertainties which could cause actual events or results to differ materially from those reflected in the forward-looking statements or forward-looking information, including, without limitation, risks and uncertainties relating to:

- the anticipated closing date of the Offering;
- general business and economic conditions;
- the intention to complete the listing on the CSE of the Unit Shares and the Warrant Shares;
- the anticipated use of the net proceeds of the Offering;
- the terms of the Offering (including the manner of distribution);
- financial and other projections, future plans, objectives, performance, revenues, growth, profits or operating expense;
- effect of the novel coronavirus (“COVID-19”) outbreak on the ability of the Company to carry on business;
- the use of available funds;
- the Company’s plans to develop, obtain regulatory approval for and commercialize its lead product candidates;
- expectations with respect to regulatory approvals of the Company’s products;
- the ailments for which the Company’s intended pharmaceutical products will be used to treat;
- the perceived benefits of the Company’s product candidates over other treatments for infectious diseases;
- the Company’s expectations regarding its revenue, expenses and research and development operations;
- the Company’s ability to conduct successful clinical trials for its product candidates;
- requirements for additional capital and future financing options;
- acceptance of the Company’s products in different markets;
- the intended outcome of collaborations with third parties, including, without limitation, the expected results of clinical trials and the expected timing of regulatory applications;
- expectations with respect to changes to applicable regulatory regimes;

- the Company's treatment under regulatory regimes and applicable laws;
- the Company's anticipated agreements with third parties, including, without limitation, the terms thereof, the timing of such agreements, the expected outcomes of such agreements and the geographic locations of such parties;
- manufacturing and distribution partnerships and agreements;
- plans related to marketing, distribution and production;
- future plans, objectives or economic performance, or the assumption underlying any of the foregoing;
- the Company's planned business objectives and future dividend policy; and
- other expectations of the Company.

Should one or more of these risks and uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in forward-looking statements or forward-looking information. Although the Company has attempted to identify important factors that could cause actual results to differ materially, there may be other factors that could cause results not to be as anticipated, estimated or intended. For more information on the Company and the risks and challenges of its business, investors should review the Company's annual filings that are available at [www.sedar.com](http://www.sedar.com). The Company provides no assurance that forward-looking statements or forward-looking information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements and information. Accordingly, readers should not place undue reliance on forward-looking statements and forward-looking information. Any forward-looking statement speaks only as of the date on which it is made and, except as may be required by applicable securities laws, the Company disclaims any intent or obligation to update any forward-looking information, whether as a result of new information, changing circumstances, or otherwise.

## SUMMARY DESCRIPTION OF BUSINESS

### What is our Business?

The Company is a life sciences company focused on the research and development of therapeutics for infectious diseases and rare disorders, and it is prioritizing drug development efforts to take advantage of several regulatory incentives awarded by the U.S. Food and Drug Administration ("FDA") such as Orphan Drug, Fast Track, Breakthrough Therapy and Rare Pediatric Disease designations. Currently, the Company is exploring the use of Bucillamine for the potential treatment of infectious diseases, with an initial focus on severe influenza and COVID-19. The Company is also advancing the development of psilocybin-based therapeutics in various diseases and disorders. It also maintains a cannabinoid pharmaceutical portfolio focused on rare inflammatory diseases. The Company was granted FDA orphan drug status designation for the use of cannabidiol ("CBD") to treat autoimmune hepatitis (liver disease) and to treat ischemia and reperfusion injury from organ transplantation. The Company 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 for its product candidates. 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.

### Recent Developments

#### *Bucillamine*

Over the course of fiscal year 2022, the Company:

- The Company continued with its FDA Phase 3 clinical trial (the "Study") to evaluate the safety and efficacy of Bucillamine in patients with mild to moderate COVID-19.

The Study is a randomized, double-blind, placebo-controlled trial and the safety and efficacy data at each remaining interim analysis timepoint, which currently are 600 and 800 completed patients, are only made available to the Independent Data and Safety Monitoring Board (“**DSMB**”) for review and recommendations on continuation, stopping or changes to the conduct of the Study.

The Study has not, to date, seen any serious adverse events or safety concerns that required the DSMB to be notified or take action on. In the event of any serious safety concerns, the DSMB would be notified to determine any risks and provide its recommendations.

The Company partnered with 47 clinical sites in fourteen states including: Alabama, Arkansas, California, Florida, Georgia, Illinois, Michigan, Nevada, New York, North Carolina, Ohio, South Carolina, Tennessee and Texas; also one clinical site in Puerto Rico.

- Further to the DSMB review and recommendations on each interim analysis periods, the Company is preparing for the potential of filing an Emergency Use Authorization (“**EUA**”) with the FDA in the event that the blinded results provide evidence to the DSMB to recommend pursuing EUA for Bucillamine to treat mild to moderate COVID-19 or a Pre-New Drug Application submission with FDA.

The Company also commenced discussions with reputable international pharmaceutical companies seeking to obtain commercial rights to Bucillamine as a treatment for COVID-19 in various countries in Europe, India and Asia. In light of these discussions, Revive pursued commercialization plan that would leverage the clinical results from the U.S. Phase 3 study to allow for drug approvals globally.

- In light of the spread of the Delta variant of COVID-19 and as a follow on to a recent study, titled “Thiol-based drugs decrease binding of SARS-CoV-2 spike protein to its receptor and inhibit SARS-CoV-2 cell entry”<sup>1</sup> showing that thiol-based drugs, like Bucillamine, decrease the binding of SARS-CoV-2 spike protein to its receptor, decrease the entry efficiency of SARS-CoV-2 spike pseudotyped virus, and inhibit SARS-CoV-2 live virus infection, the Company supported research under its sponsored agreement with the University of California, San Francisco (“**UCSF**”) in the laboratory of Dr. John Fahy to explore the utility of thiol-based drugs, including Bucillamine, against the Delta variant of COVID-19.
- The Company has also decided to incorporate viral load testing to complement the Study to a minimum of 300 patients that will be enrolled in the Study. The viral load will allow the Company to quantify the speed in which Bucillamine can reduce viral infection of patients throughout the course of treatment, thus allowing to understand the most optimal time to introduce Bucillamine in the treatment course and provide confidence in the potential utility and effectiveness of Bucillamine in COVID-19.
- The Company filed an application with the FDA to receive Orphan Drug Designation (“**ODD**”) for Bucillamine for the prevention of ischemia–reperfusion injury (“**IRI**”) during liver transplantation. In February 2022 that the FDA has granted ODD for Bucillamine for the prevention of IRI during liver transplantation.
- The Company expanded the Study to evaluate whether Bucillamine can be used as a potential treatment for the Omicron variant (B.1.1.529)
- The Company, in collaboration with Delta Health, received approval by the Ethics Committee of Istinye University in Turkey to expand the Study into Turkey. The Company is working with MLP Care, the largest hospital group in Turkey, and Istinye University with access to 30 clinical research sites and over 6000 in-patient hospital beds.

- The Company submitted a request to the FDA to determine and agree on the Study's potential new primary efficacy endpoints, including the rate of sustained clinical resolution of symptoms of COVID-19 which addresses the shift in COVID-19 clinical outcome observed over the course of the pandemic, and, therefore, to have more meaningful study endpoints for the FDA to consider for potential regulatory approval.

The FDA agreed that the Company may unblind the pre-dose-selection data for the first 210 patients of the Study to further support the new primary endpoint. Before unblinding the pre-dose selection data for the first 210 patients, the Company submitted a Data Access Plan to the FDA in early June 2022 with the aim to unblind the pre-dose selection data and submit the amended Study protocol with the new primary efficacy endpoints to the FDA.

- The Company amended the Study protocol with the proposed new primary efficacy endpoints and submit to the FDA for further discussion and agreement. The proposed new primary efficacy endpoints include the time to resolution from COVID-19 via the polymerase chain reaction (“PCR”) test and the rate of sustained clinical resolution of certain symptoms of COVID-19. The proposed endpoints address the shift in COVID-19 clinical outcomes observed over the course of the pandemic, and, therefore, have more meaningful study endpoints for the FDA to consider for regulatory approval.
- The FDA advised the Company that a Type C meeting would be recommended, which the Company requested, to discuss the overall development plan and the latest revised endpoints for the Study to evaluate the safety and efficacy of Bucillamine. The FDA requested additional information, which would include clinical data, for them to agree on the Study's revised endpoints.

The Company anticipates submitting its Type C meeting request package to the FDA by mid-December 2022, which will outline the overall development plan and Pre-Dose selection data supporting the latest revised endpoints for the Study. Following the submission of the Type C meeting request package, the Company expects to hear from the FDA on a firm date for the meeting.

### *Psychedelics*

Over the course of fiscal year 2022, the Company:

- The Company commenced working with the Board of Regents of the University of Wisconsin System under a clinical trial agreement to conduct a Phase I/II clinical study to evaluate the safety and feasibility of psilocybin in adults with methamphetamine use disorder. Study start-up activities have taken place and enrollment activities commenced. As a result of the study, clinical data will provide proprietary and valuable information on the safety, efficacy and dosing of psilocybin to support future pivotal FDA clinical studies in oral forms of delivery including oral thin film strips. The clinical study will be conducted at the University of Wisconsin-Madison, School of Medicine and Public Health and School of Pharmacy, which holds a Wisconsin special authorization and DEA license to perform clinical research with psilocybin. In addition, the Company will have exclusive access to key intellectual property from this study to support development, regulatory and commercial initiatives.
- The Company is advancing the research and intellectual property acquired from PharmaTher Holdings Ltd. on psilocybin as a potential solution to managing TBI and stroke. Preclinical studies demonstrated that psilocybin, given after injury, improved cognitive function in TBI mice. The Company is proceeding to an FDA clinical study to be conducted at the University of Wisconsin-Madison, School of Medicine and Public Health and School of Pharmacy.
- The Company initiated the product development program under a feasibility agreement with LTS Lohmann TherapieSysteme AG, to develop and manufacture a proprietary psilocybin oral thin film strip for mental

illness, substance abuse and neurological disorders. Research grade prototypes will be available to evaluate dosing and delivery rates in various dosage forms with the expectation to conduct clinical studies in the near future.

- Under its research collaboration with North Carolina State University (“**NC State**”), the Company is developing a novel biosynthetic version of psilocybin based on a natural biosynthesis enzymatic platform developed by Dr. Gavin Williams, Professor and Researcher at NC State. The biosynthetic platform developed by Dr. Gavin Williams provides a potentially simple and efficient method for rapidly producing natural products, such as psilocybin, using an engineered enzymatic pathway in *E. coli*. Certain technical milestones have been achieved to date, offering a clear path towards completing validation methods to demonstrate a novel yet simple production process of biosynthetic psilocybin that can be used at a critical scale for clinical and commercial use.
- The Company entered into an agreement with the University of Health Sciences Antigua to utilize the Company’s novel psychedelic-assisted therapies including its tannin-chitosan delivery system and to pioneer the clinical research and development of psychedelics in Antigua and Barbuda. Clinical research will be conducted at the university with the aim for commercialization in Antigua and Barbuda. Once approved for sale, the Company will seek commercial partnerships with specialty pharmaceutical companies in the Caribbean and Latin America.
- The Company entered into an exclusive license agreement (the “**PR Agreement**”) with Puerto Rico Science Technology and Research Trust (“**PRSTRT**”), representing Universidad Central del Caribe (“**UCC**”) and St. Jude Children’s Research Hospital (“**St. Jude**”), for the intellectual property titled, Biologically Active Ganoderma Lucidum Compounds and Synthesis of Anticancer Derivatives; Ergosterol Peroxide Probes for Cellular Localization. Researchers at St. Jude and UCC have characterized medicinal mushroom Ganoderma lucidum compounds with anti-cancer activity, specifically significant activity against breast cancer, thus having the potential to treat the most aggressive types of breast cancers such as triple negative breast cancer and inflammatory breast cancer.

Under the terms of the PR Agreement, the Company gained exclusive worldwide development and commercial rights to the intellectual property. The Company, PRSTRT and St. Jude agreed to terms consistent with industry standards, including future payments based on clinical trial and revenue milestones.

- The Company entered into a research collaboration agreement with PharmaTher Holdings Ltd. (“**PharmaTher**”) to evaluate the delivery of psilocybin with PharmaTher’s proprietary microneedle (“**MN**”) patch technology for neuropsychiatric disorders.

PharmaTher is currently conducting IND-enabling research studies with MicroDose-MN™, a patent-pending biocompatible and biodegradable gelatin methacryloyl microneedle patch, to deliver psilocybin to support an IND application with the FDA for clinical studies.

The collaboration agreement will give the Company the ability to evaluate the MicroDose-MN™ for psilocybin program to support upcoming clinical and commercial developments globally.

## Material Facts

There are no material facts about the securities being distributed that have not been disclosed in this offering document or in any other document filed by the Company in the 12 months preceding the date of this offering document.

There can be no guarantee that the Company will be successful in raising the maximum amount under this Offering.

## **Business Objectives and Milestones**

### **What are the business objectives that we expect to accomplish using the available funds?**

The Company intends to use the net proceeds from the Offering to (i) provide the FDA with the necessary data to revise the Study's endpoints, via a Type C meeting request (ii) continue ongoing activities and enroll subjects in the Study and (ii) continue with the development of its psychedelics program.

In the event that the FDA permits the Company to revise the Study's endpoints, the Company will need to do the following in order to complete the Study:

- complete DSMB meeting to review and determine the completed post-dose selection data of approximately 500 subjects in the context of the new primary endpoint. The DSMB may recommend continuing the Study if there is a trend toward achieving statistical significance, halting the Study early due to statistical significance likely not going to be met, or halting the Study early due to positive efficacy showing statistical significance;
- complete DSMB meeting to review and determine the completed post-dose selection data of approximately 800 subjects, pending further recruitment ; and
- potential Pre-New Drug Application submission with FDA.

In the event that the Company is not permitted to revise the endpoints, the Company will need to do the following in order to complete the Study:

- complete DSMB meeting to review and determine the completed post-dose selection data of approximately 500 subjects in the context of the existing endpoint and protocol. The DSMB may recommend continuing the Study if there is a trend toward achieving statistical significance, halting the Study early due to statistical significance likely not going to be met, or halting the Study early due to positive efficacy showing statistical significance;
- complete DSMB meeting to review and determine the completed Post-Dose selection data of approximately 800 subjects, pending further recruitment and
- potential Pre-New Drug Application submission with FDA.

With the anticipated minimum funding, the Company's priority is to provide the FDA with the necessary data to revise the Study's endpoints. Should the Company raise the maximum funding, the Company's priority is to provide the FDA with the necessary data to revise the Study's endpoints and to complete the Study pending DSMB feedback in fiscal 2023.

## **USE OF AVAILABLE FUNDS**

### **Available Funds**

#### **What will our available funds be upon the closing of the offering?**

The expected availability of funds is \$368,886 and \$2,208,886 for the minimum and maximum offering size, respectively.

		<b>Assuming minimum offering only</b>	<b>Assuming 100% of this offering</b>
A	Amount to be raised by this offering	\$3,000,000	\$5,000,000
B	Selling commissions and fees	\$240,000	\$400,000
C	Estimated offering costs (e.g. legal, accounting, audit)	\$85,000	\$85,000
D	Net proceeds of offering: D=A – (B+C)	\$2,675,000	\$4,515,000
E	Working capital as at most recent month end (deficiency)	\$(2,306,114)	\$(2,306,114)
F	Additional sources of funding	\$-	\$-
G	Total available funds: G = D+E+F	\$368,886	\$2,208,886

**Use of Available Funds**

**How will we use the available funds?**

<b>Description of intended use of available funds listed in order of priority</b>	<b>Assuming minimum offering only</b>	<b>Assuming 100% of offering</b>
Provide the necessary data to revise the Study’s endpoints	\$215,000	\$215,000
The continuation and completion of the Study	-	\$1,500,000
The development of the psychedelics program	-	\$340,000
General & administration	\$153,886	\$153,886
<b>Total:</b>	<b>\$368,886</b>	<b>\$2,208,886</b>

The above noted allocation and anticipated timing represents the Company’s current intentions with respect to its use of proceeds based on current knowledge, planning and expectations of management of the Company. Although the Company intends to expend the proceeds from the Offering as set forth above, there may be circumstances where, for sound business reasons, a reallocation of funds may be deemed prudent or necessary and may vary materially from that set forth above, as the amounts actually allocated and spent will depend on a number of factors, including the Company’s ability to execute on its business plan.



**Use of Funds from Previous Financings**

**How have we used the other funds we have raised in the past 12 months?**

Date of Financing and Funds Raised	Intent of Use of Funds	Explanation of Variances	Impact of Variances on Business Objectives and milestones
February 9, 2021, Prospectus Offering Raising gross proceeds of \$23,000,000	\$9,000,000 – Bucillamine Phase 3 Study	\$19,310,065 used for the Phase 3 Study	The Company allocated additional funds to the study in order to increase the number of subjects from 400 to 710.
	\$4,000,000 - Psilocybin research and development	\$729,897 used for Psilocybin research and development	The Company decided to focus its attention and efforts on its Phase 3Study and allocated additional funds towards the study.
	\$2,000,000 – Discovery research and formulation development exploring novel uses of Bucillamine for infectious diseases, liver diseases, and other psychedelic compounds for various disorders in pre-clinical models	\$1,029,424 used for the discovery research and formulation development	The Company decided to focus its attention and efforts on its Phase 3Study and allocated additional funds towards the study.
	\$3,050,000 – Working capital and general corporate purposes	\$3,205,353 used for working capital and general corporate purposes	

**FEES AND COMMISSIONS**

**Involvement of dealers or finders and their fees**

**Who are the dealers or finders that we have engaged in connection with this offering, if any, and what are their fees?**

The Company has engaged EMD Financial Inc., a registered exempt market dealer, to assist with the Offering. The Company will pay EMD Financial Inc. as well as any other registrants participating in the Offering a finder’s fee comprised of a cash commission of up to 8% of the gross proceeds of the Offering and non-transferable finder warrants of up to 8% of the number of Units. Such finder warrants shall entitle the holder to acquire one common

share of the Company at a price of \$0.15 per common share for a period of 36 months.

### **Dealer Conflicts**

#### **Do(es) the dealer(s) have a conflict of interest?**

To the knowledge of the Company, it is not a “related issuer” or “connected issuer” of or to the dealer, as such terms are defined in National Instrument 33-105 – Underwriting Conflicts.

## **PURCHASERS’ RIGHTS**

### **Purchasers’ rights**

#### **Rights of Action in the Event of a Misrepresentation**

**If there is a misrepresentation in this offering document, you have a right**

- a. to rescind your purchase of these securities with the Company, or**
- b. to damages against the Company and may, in certain jurisdictions, have a statutory right to damages from other persons.**

**These rights are available to you whether or not you relied on the misrepresentation. However, there are various circumstances that limit your rights. In particular, your rights might be limited if you knew of the misrepresentation when you purchased the securities.**

**If you intend to rely on the rights described in paragraph (a) or (b) above, you must do so within strict time limitations.**

**You should refer to any applicable provisions of the securities legislation of your province or territory for the particulars of these rights or consult with a legal adviser.**

## **ADDITIONAL INFORMATION**

### **Additional Information**

#### **Where can you find more information about us?**

Security holders can access the Company's continuous disclosure at [www.sedar.com](http://www.sedar.com) and on the Company's website <https://revivetherapeutics.com>.

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**DATE AND CERTIFICATE****Certificate**

This offering document, together with any document filed under Canadian securities legislation on or after November 30, 2021, contains disclosure of all material facts about the securities being distributed and does not contain a misrepresentation.

Dated: November 30, 2022

*(Signed) Michael Frank*

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**Michael Frank**  
**Chief Executive Officer**

*(Signed) Carmelo Marrelli*

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**Carmelo Marrelli**  
**Chief Financial Officer**