# A SPECIALTY LIFE SCIENCES COMPANY

Corporate Presentation
OCTOBER 2021





US: RVVTF

FRANKFURT: 31R

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## FORWARD LOOKING STATEMENTS



Certain statements contained in this presentation constitute forward-looking information within the meaning of securities laws. Forwardlooking information may relate to our future outlook and anticipated events or results and may include statements regarding our future financial position, business strategy, budgets, litigation, projected costs, capital expenditures, financial results, taxes and plans and objectives. In some cases, forward-looking information can be identified by terms such as "may", "will", "should", "expect", "plan", "anticipate", "believe", "intend", "estimate", "predict", "potential", "continue" or other similar expressions concerning matters that are not historical facts. These statements are based on certain factors and assumptions regarding, among other things, expected growth, results of operations, performance, and business prospects and opportunities. While we consider these assumptions to be reasonable based on information currently available to us, they may prove to be incorrect. Forward looking-information is also subject to certain factors, including risks and uncertainties that could cause actual results to differ materially from what we currently expect. These factors include, among other things, the availability of funds and resources to pursue development projects, the successful and timely completion of clinical studies, and the ability to take advantage of business opportunities, the granting of necessary approvals by regulatory authorities, and general economic, market and business conditions. For more exhaustive information on these risks and uncertainties you should refer to our most recently filed Annual Information Form which is available at www.sedar.com. Forward-looking information contained in this presentation is based on our current estimates, expectations and projections, which we believe are reasonable as of the current date. You should not place undue importance on forward-looking information and should not rely upon this information as of any other date. While we may elect to, we are under no obligation and do not undertake to update this information at any particular time.

## **REVIVE THERAPEUTICS**





Specialty life sciences company focused on repurposing drugs for rare disorders and infectious diseases



FDA approved Phase 3 clinical trial for Bucillamine in the treatment of COVID-19

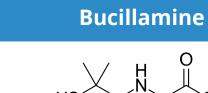


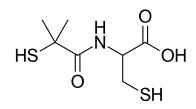
Developing novel Psilocybin and Cannabidiol therapeutics for various CNS and inflammatory disorders



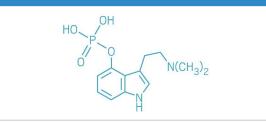


Near-team value creation milestones

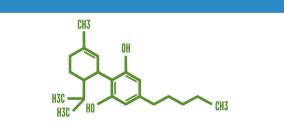




### **Psilocybin**



### **Cannabidiol**

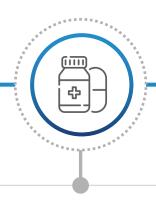




Robust patent portfolio covering methods and compositions of drugs

## PHARMACEUTICAL STRATEGY











Clinical development of Psilocybin, Cannabidiol and Bucillamine

Targeting Rare
Disorders and
Infectious Diseases,
Neurological Disorders,
Mental Health and
Liver Diseases

Novel Uses, Formulations, and Delivery System Targeting FDA
Designations:
Orphan, Fast track,
Breakthrough
therapy



# **PATENT PORTFOLIO**



Title Title	USPTO No.	Status
Use of Bucillamine in the Treatment of Infectious Diseases, including COVID-19	62/991,996	Provisional patent filed
Use of Bucillamine in the Treatment of Gout	US9662305	Issued on May 30, 2017
Drug Delivery System	US 8642088 US 9545423 US 10104888	Issued on February 4, 2014 Issued on January 17, 2017 Issued on October 23, 2018
Psilocybin effervescent and psilocybin tablet - Solid Oral Pharmaceutical Compositions	62/985,052	Provisional patent filed
Psilocybin hard-shell capsules - Pharmaceutical Capsule Compositions	62/985,070	Provisional patent filed
Psilocybin gum drops - Pharmaceutical Gumdrop Compositions	62/985,084	Provisional patent filed
Psilocybin oral strips and transmucosal - Thin-Film Pharmaceutical Delivery System and Formulations	62/985,098	Provisional patent filed
Psilocybin - Pharmaceutical Formulations and Methods for Sublingual and Buccal Administration	62/984,590	Provisional patent filed
Methods for the Extraction and Crystallization of Psilocybin	62/985,360	Provisional patent filed
Psilocybin in the Treatment of Neurological Brain Injury	63/011,493	Provisional patent filed
Use of Psilocybin in the Treatment of Cancer	63/133,913	Provisional patent filed
Psilocybin Pharmaceutical Combination Therapies	63/125,106	Provisional patent filed
Use of Cannabidiol in the Treatment of Autoimmune Hepatitis	US 8242178	Issued on August 14, 2012

## **PRODUCT PIPELINE**

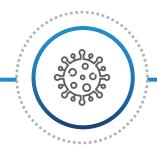


## **Focus on Infectious Diseases, Psychedelics and Rare Disorders**

Product	Indication	Stage of Development	Regulatory Status
Bucillamine	Infectious Diseases COVID-19	Phase 3 (COVID-19)	FDA approved for Phase 3
Psilocybin	Substance Use Disorder Methamphetamine	Phase 1	CTA with University of Wisconsin
Psilocybin	Neurological TBI (Concussion), Stroke	Pre-clinical	Target FDA Orphan Drug Approval
Psilocybin (Oral Formulations)	Mental Health Depression, Anxiety	Pre-clinical	Target FDA Approval
Cannabidiol CBD	Liver Diseases Autoimmune Hepatitis	Filing IND	Plan for Phase 2

## INFECTIOUS DISEASE OPPORTUNITY











# Received FDA approval for FDA Phase 3 clinical trial for COVID-19

Phase 3 study is ongoing

# Focus on Bucillamine in the treatment of infectious diseases

 Well-known safety profile and prescribed for arthritis in Japan and South Korea for over 30 years

# Revive's clinical history with Bucillamine

- Obtained 2 FDA INDs with Bucillamine and FDA orphan drug status
- FDA Phase 2 clinical study for acute gout flares and cystinuria

# Bucillamine scientific rationale as an intervention for COVID-19 (see Appendix)

- BUC is 16x more potent than particularly N-acetylcysteine (NAC); NAC has shown to prevent acute lung injury caused by influenza virus
- BUC shown superior function in restoring glutathione and therefore greater potential to prevent acute lung injury during influenza infection
- BUC also shown to prevent oxidative and reperfusion injury in heart and liver tissues
- BUC proven safety and MOA similar to NAC, but with much higher potency

## **PSYCHEDELICS OPPORTUNITY**





### **Acquired Psilocin Pharma Corp.**

- Derrick Welch, Founder with 14 years of HC experience; 5 years in Cannabis
- Worked with Xanthic Bio Pharma and Green Growth Brands
- Developed water Soluble THC and CBD products (Beverages, effervescent tablets)



# Acquired Psilocybin Program from <a href="PharmaTher Inc.">PharmaTher Inc.</a> (CSE: PHRM, OTCQB: <a href="PHRRF">PHRRF</a>)

- IND-enabling research for traumatic brain injury (concussion) and stroke.
- Expansion to other neurological and cancer indications (FDA orphan drug)



## **Psilocybin Oral Thin Film formulation**

 Collaboration development with LTS Lohmann and University of Wisconsin-Madison



### **Novel Psilocybin Biosynthesis Enzymatic Platform**

 Collaboration with NCSU, under Dr. Gavin Williams, to develop a simple method for rapidly producing psilocybin using an engineered enzymatic pathway in E. coli











## FORMULATION & DELIVERY TECHNOLOGY



# Delivering naturally extracted and synthetic psychedelics and cannabinoids



#### **DELIVERY SYSTEM**

Combines **Tannin** (antibacterial, antifungal, antioxidant, wound healing) and **Chitosan** (blood-clotting and antimicrobial) composites

 Releases (rapid, controlled, sustained), improved bioavailability, no first-pass metabolism



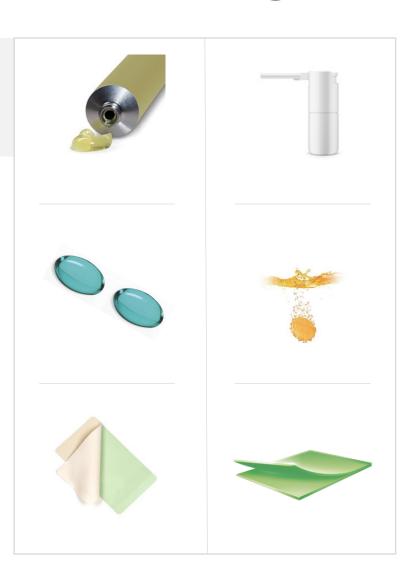
#### **PSILOCYBIN**

Precise dosed formulations i.e. capsules, sublingual spray, gel caps, effervescent tablets and oral/transmucosal strips



#### **CANNABIDIOL**

Novel combination of composites allowing for multiple delivery formats, potential synergistic and therapeutic effects



## LIVER DISEASE OPPORTUNITY



## **Focus on Autoimmune Hepatitis (AIH)**



AIH - rare disease (~76k patients in **US) causing liver inflammation** 

**Drawbacks of current therapies (steroids):** 

Severe side effects in 13%, relapse after drug withdrawal in 50%-86%\*



**Obtained FDA orphan drug status for CBD in the** treatment of AIH



Seeking to file FDA IND to conduct Phase 2 clinical study in patients affected by AIH

## **Big Pharma interest in liver diseases**



Allergan acquisition of Tobira for

\$1.7 billion



**b** NOVARTIS

Novartis license of Conatus drug for

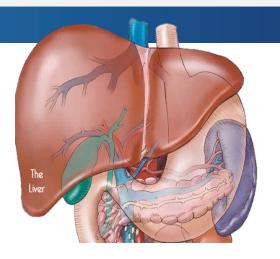
\$650 million



**GILEAD** 

Gilead acquisition of Nimbus for

\$1.2 billion



## **STRATEGIC PARTNERS**





Infectious Diseases CRO



Psilocybin Oral Thin Film Delivery Collaboration



R&D partnership Psychedelic pharma



License of cannabidiol for treatment of Autoimmune Hepatitis



Psilocybin Biosynthesis Collaboration



Psilocybin Collaboration

## **EXPECTED MILESTONES**





### FDA EUA Approval for Bucillamine in the treatment of COVID-19

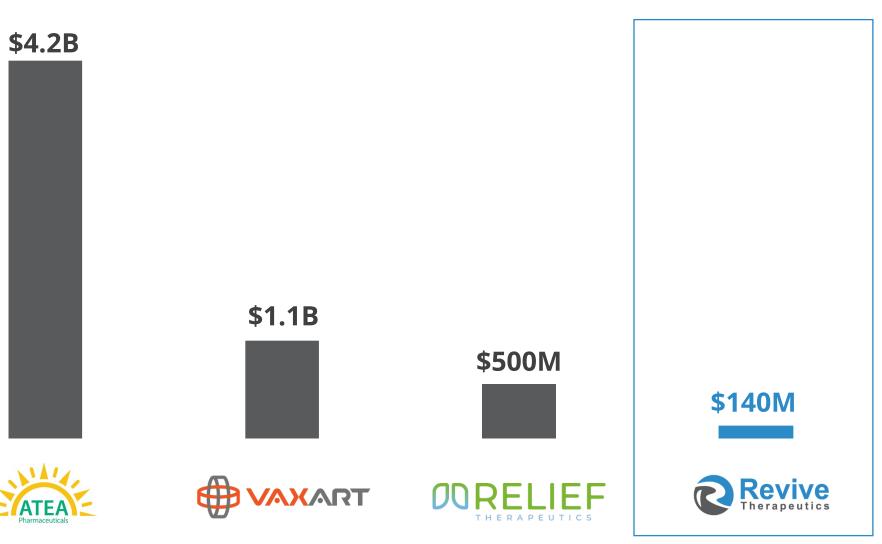
- Complete Enrollment of Phase 3 study of Bucillamine in the treatment of COVID-19
- Phase 2 study for Psilocybin (Methamphetamine Use Disorder) at University of Wisconsin
- Initiate Phase 2 study for Psilocybin (TBI Concussion) at University of Wisconsin

- FDA pre-IND meeting for Psilocybin oral thin film
- Scale up of Psilocybin oral thin film for FDA IND
- Initiate Phase 2 clinical study of CBD in the treatment of Autoimmune Hepatitis

# PEER COMPARISON - COVID (MARKET CAPS)

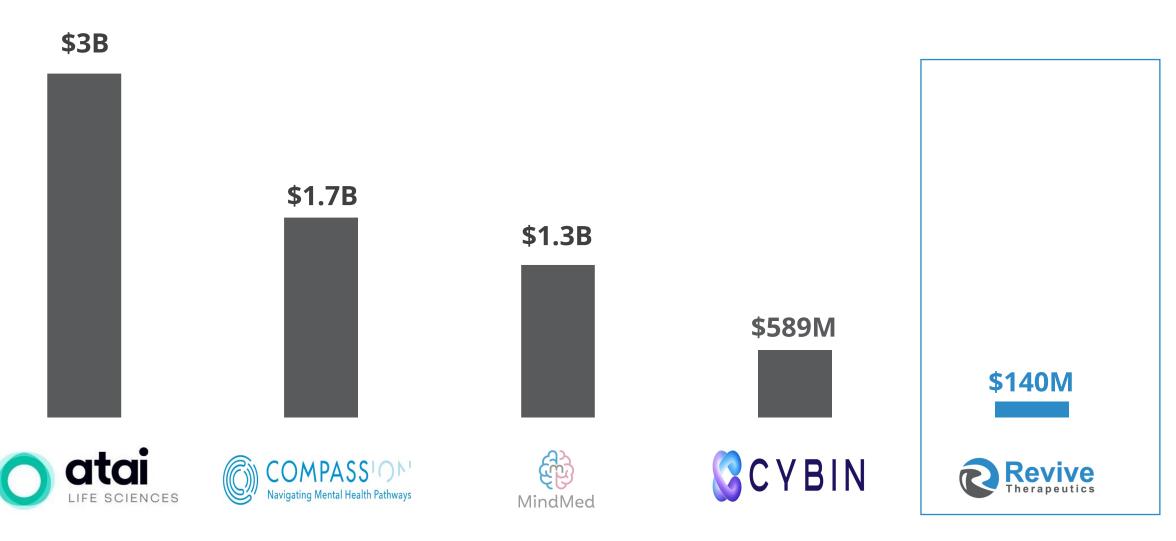


Market Caps in \$ CAD



# PEER COMPARISON - PSYCHEDELICS (MARKET CAPS) Revive





Market Caps Fully-diluted and in \$ CAD

## **TEAM**





### Management

- Michael Frank
   Chairman and CEO
- Carmelo Marrelli
   Chief Financial Officer
- Derrick Welsh
   Founder, Psilocin Pharma Corp.



## **Clinical & Regulatory**

- Dr. Kelly McKee, Jr., MD, MPH
   Chief Scientific Officer, Consultant
- Dr. Onesmo Mpanju, PhD
   FDA Regulatory Affairs, Consultant
- Dr. Joel Moody, MD, MPH, DTM&H
   Epidemiologist, Medical & Clinical, Consultant
- Dr. John Fahy, MD
   Pulmonary and critical care,
   Scientific & Clinical, Consultant



### **Board of Directors**

- Michael Frank
   Chairman and CEO
- William Jackson
   Director
- Joshua Herman Director
- Christian Scovenna Director
- Andrew Lindzon
   Director

## **STOCK INFORMATION**





**Ticker** 

RVV (CSE) | RVVTF (OTCQB) | 31R (Frankfurt)



52-Week High/Low

CAD \$0.92 / \$0.175



**Market Cap** 

CAD ~ \$135,000,000



**Share Price** 

CAD \$0.43 (October 5, 2021)



**Capital Structure** 

315,634,551 common shares

# **APPENDIX – BUCILLAMINE SCIENTIFIC RATIONALE FOR COVID-19**



Current antiviral interventions for influenza have exhibited modest efficacy, especially in improving mortality in at-risk populations, such as the elderly. Novel antivirals have been plagued by poor oral bioavailability and lack of efficacy when not delivered early. This is because these drugs mostly act to prevent the early processes of virus binding to cells or viral replication. Thiols, particularly N-acetylcysteine (NAC), with antioxidant and reducing activity have been investigated as effective therapies that abrogate the potential for influenza to cause severe disease. Restoration of glutathione, the major intracellular thiol antioxidant, is a critical functional activity of NAC. Reactive oxygen species (ROS) generation during influenza virus infection aggravate destructive inflammation and programmed death of epithelial cells. Studies in human cells and animal models have shown that NAC works to prevent acute lung injury caused by influenza virus infection through inhibition of these ROS-mediated mechanisms. NAC has been investigated clinically and found to significantly attenuate clinical symptoms associated with influenza infection, especially in elderly at-risk patients. While NAC is easily taken up by cells and has low toxicity, clinical efficacy has required long-term and high-dose administration because of modest relative potency, limiting its clinical applicability.

Bucillamine (N-(mercapto-2-methylpropionyl)-l-cysteine), which has a well-known safety profile and is prescribed in the treatment of rheumatoid arthritis in Japan and South Korea for over 30 years, is a cysteine derivative with 2 thiol groups that is 16-fold more potent than NAC as a thiol donor in vivo, giving it vastly superior function in restoring glutathione and therefore greater potential to prevent acute lung injury during influenza infection. Bucillamine has also been shown to prevent oxidative and reperfusion injury in heart and liver tissues and is highly cell permeable for efficient delivery into cells. Bucillamine has unrealized potential for the treatment of influenza with both proven safety and proven mechanism of action similar to that of NAC, but with much higher potency, mitigating the previous obstacles to using thiols therapeutically. It is also reasonable to hypothesize that similar processes related to ROS are involved in acute lung injury during nCov-19 infection, possibly justifying the investigation of Bucillamine as an intervention for COVID-19.

# APPENDIX – BUCILLAMINE SCIENTIFIC RATIONALE FOR COVID-19



### References

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- 2. Duwe S. Influenza viruses antiviral therapy and resistance. GMS Infect Dis. 2017; 5: Doc04.
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- 6. Poole LB. The Basics of Thiols and Cysteines in Redox Biology and Chemistry. Free Radic Biol Med. 2015 Mar; 0: 148–157. doi: 10.1016/j.freeradbiomed.2014.11.013.
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