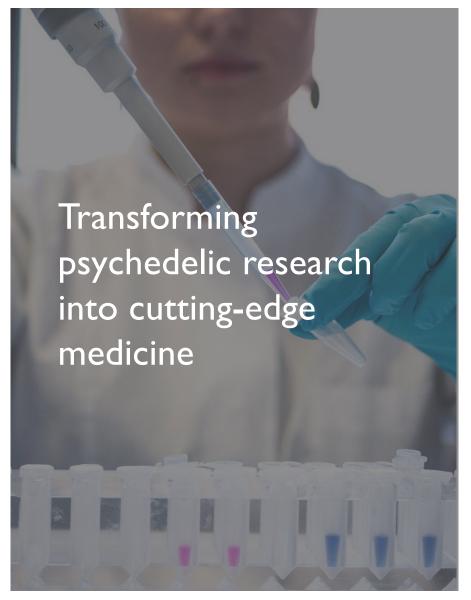


Transformational Medicines for Neurological & Psychiatric Disorders

CORPORATE OVERVIEW



Ceruvia Lifesciences researches, develops, and manufactures neurotransformational medicines to deliver meaningful relief to patients suffering from challenging, hard-to-treat headache and psychiatric disorders

- **Developing two novel compounds across numerous** therapeutic areas
  - BOL-148 in Headache and Addiction Disorders
  - · Psilocybin in Headache and Obsessive-Compulsive Disorder
- Over ten years of funding and coordinating academic research in neurotransformational and psychedelic medicine
  - Involvement with leading research and development institutes in psychedelic medicine
  - Development programs in partnership with leading medical centers

**150** 

## Life sciences expertise that delivers scientific rigor

- Expert technical team with over 150 years industry experience
- Scientific advisors from leading research institutes across USA and Europe



# Our strategic focus is on realizing the value of our pipeline assets



### **Fund**

Position ourselves as therapeutic leaders by targeting funding into difficult-to-treat disease areas with great unmet need



# **Provide Evidence**

Generate robust scientific clinical data from controlled clinical trials with innovative collaborators, partners, academia and industry experts to progress the projects



# Advance

As the world's first manufacturer of GMP LSD and GMP BOL-148, we adhere to the highest development, testing, and manufacturing standards as established by regulatory authorities as well as pharmaceutical industry associations and organizations

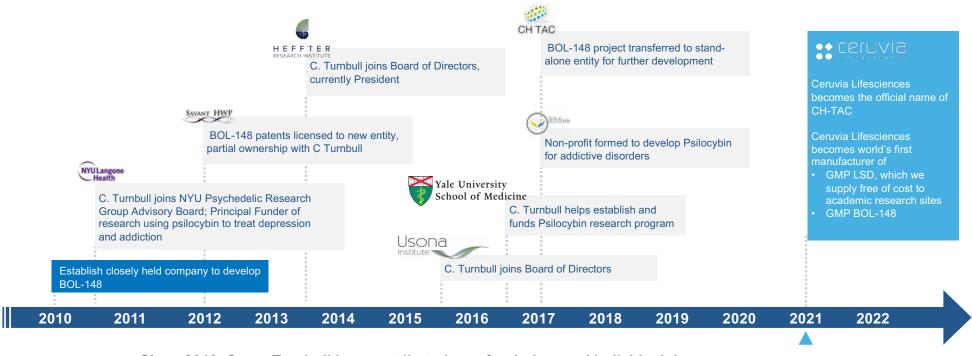


### Commercialize

Ceruvia Lifesciences aims to ultimately deploy treatments to create a significant benefit for all stakeholders in our focus areas: patients, caregivers, payers, and healthcare providers



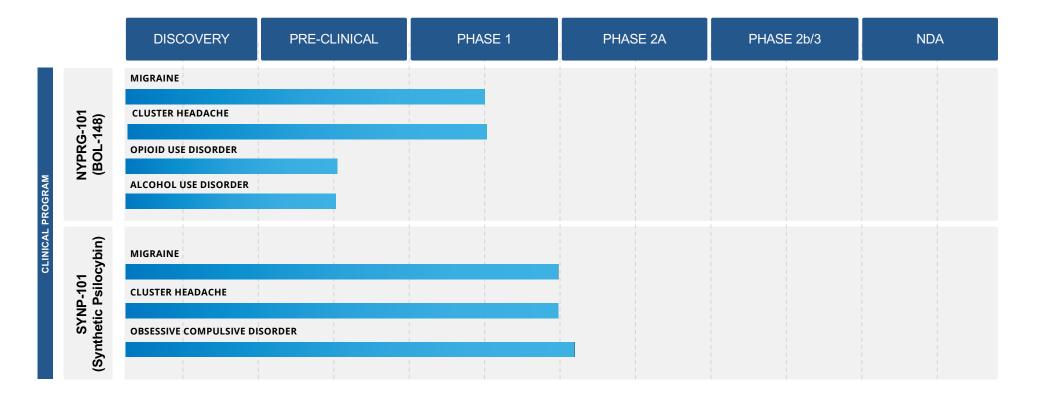
# Over a decade of driving clinical research and progress in nuerotransformational medicines



Since 2010, Carey Turnbull has contributed as a fundraiser and individual donor over \$29 MM to Psychedelic Research



# Our Development Pipeline





# Significant burden and unmet needs in the markets we aim to address



### **Headache Disorders**

~40mm

Migraine Patients USA<sup>1</sup>

More Than Just A Headache

\$36b

Est. Annual Direct/ Indirect Costs of Migraine (USA)<sup>3</sup> 330k

Cluster Headache Patients USA<sup>2</sup>





# **Psychiatric Disorders**

3.9mm

Obsessive Compulsive Disorder Patients USA<sup>1</sup>

OCD significantly impacts patients' ability to live normal lives

79.9%

Severe OCD patients reported severe role impairment (SDS scale)<sup>2</sup>

#### SOURCE

- 1. https://migraineresearchfoundation.org/about-migraine/migraine-facts/
- 2. https://www.nimh.nih.gov/health/statistics/obsessive-compulsive-disorder-ocd
- 3. Bonafede et al, Headache 2018
- 4. Source: Schor et al, CHQ Poster, www.Clusterbusters.org, 2017

#### SOURCE:

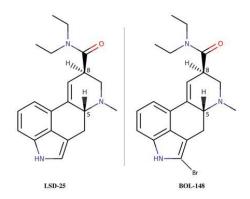
- 1. https://www.nimh.nih.gov/health/statistics/obsessive-compulsive-disorder-ocd
- 2. Source: Ruscio et al, Molecular Psychiatry 2010

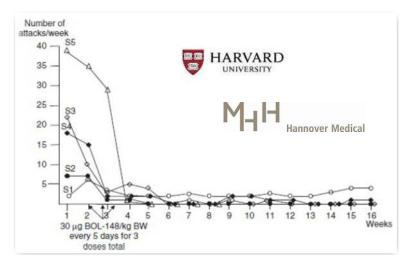


# NYPRG-101: Promising efficacy without hallucinogenic effects

# Pilot Study in Patients with Cluster Headache

- NYPRG-101 (BOL-148) is a non-hallucinogenic analog of LSD used in the past as a placebo
- Results from a pilot study in Cluster Headache suggest long-term efficacy following brief treatment
- Safely administered pre-clinically & clinically to ~300 humans



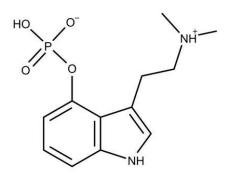


- · Open-label, uncontrolled study at Harvard/ Hannover
- 5 BOL-148 subjects, 3 oral doses over 10 days
- 100% patients reported significant relief of CH symptoms



# SYNP-101: Building on promising research at leading universities

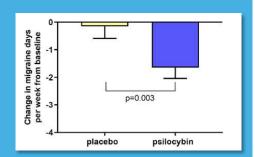
- SYNP-101 is a synthetic form of the naturally occurring compound, psilocybin, found in at least 200 species of mushrooms
- For over a decade, thousands of cluster headache sufferers have self-medicated using psilocybin with exceptional results
- Psilocybin has been shown to be safe when administered in a therapeutic setting



Exploratory study suggests there is an enduring therapeutic effect in migraine headache after a single administration of

psilocybin. Schindler et al, Neurotherapeutics (2020)





3 of 5 OCD patients randomized to receive psilocybin <u>exhibited robust</u> reductions in acute Yale-Brown Obsessive-Compulsive scores (Y-BOCS)"

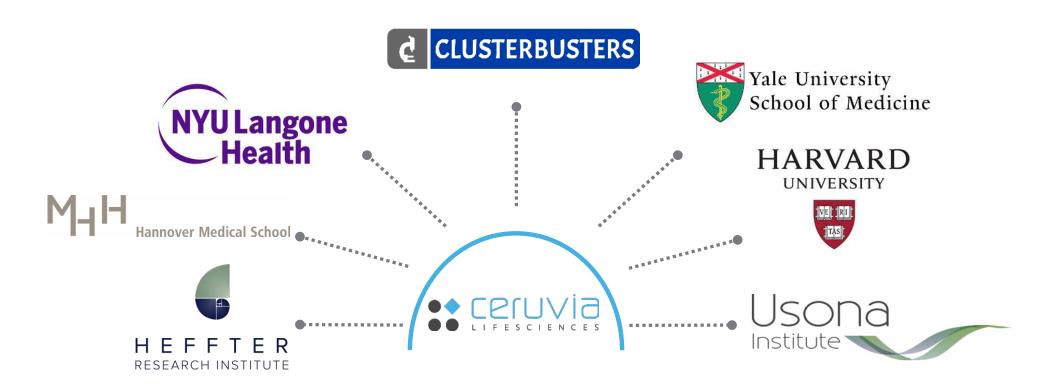
Kelmendi et al. Examining the Effect of Psilocybin in the Treatment of Treatment-Resistant OCD Poster ANCP (2020)



Based on interviews with researchers, 22 of 26 patients with cluster headache reported that psilocybin aborted attacks and 18 of 19 reported remission period extension. Sewell et al, Neurology (2006)



# Ceruvia Lifesciences has established collaborations with leading institutions and stakeholders



# Experience that knows how to deliver value



Kathleen Monroe COO20+ years Pharmaceutical Project Management



Shavne Gad, PhD, DABT Pharmacology & Toxicology 40+ years Toxicology & Pharmacology





Eric Galia **Project Lead** 20+ years CMC Development & Pharmaceutical Project Management



Jeanne Bonelle CMC, QA 40+ years in Quality Assurance and CMC development



Sophie Goubet Sieradzki Clinical Research Associate (OCD) 20+ years Clinical Research





Tom Huijbers Regulatory Affairs, R&D 20+ years Regulatory Pharmaceutical Strategist



Carey Turnbull FOUNDER / CEO 10+ years Investment/ Philanthropy in Psychedelic Medicine



Ryan Lanier, PhD **Clinical Scientist** 20+ years Pre-Clinical & Clinical **Development of CNS Drugs** 



Stephan Loose, MBA **Business Development** 15+ years Pharmaceutical Commercialization & Business Development



Amy Poshusta, PhD **Non-clinical Development** 20+ years Pharmaceutical **Drug Development** 



John Wetzel, PhD CMC 30+ years Pharmaceutical Drug Development & CMC



# Leading experts as part of the Scientific Advisory



Michael Bogenschutz, MD NYU Langone's Department of Psychiatry

Professor, Department of Psychiatry at NYU Grossman School of Medicine, Addiction & Social Anxiety Disorders





Yale University School of Medicine

- Clinical Director & Psychiatrist at VA Connecticut Healthcare System
- Director, VA-Yale Schizophrenia Research Fellowship program
- · Director, Schizophrenia Neuropharmacology Research Group at Yale (SNRGY)



Ben Kelmendi, MD

Yale University School of Medicine

· Assistant Professor of Psychiatry, Yale University School of Medicine



**Christoph Gottschalk, MD, FAHS** 

Yale University School of Medicine

- Assistant Professor of Clinical Neurology Chief, Division of General Neurology,
- Director, Fellowship Program, Headache & Facial Pain Center



Jack Henningfield, PhD Regulatory Strategy

- Vice President, Research, Health Policy, and Abuse Liability, Pinney Associates
- Adjunct Professor, Behavioral Biology, Medical School's Department of Psychiatry and Behavioral Sciences



Torsten Passie, PhD

David Nichols, PhD

of Pharmacy

Research Institute

**UNC Eschelman School of Pharmacy** 

Founding President Heffter

· Adjunct Professor UNC Eshelman School

Hannover Medical School

- Professor of Psychiatry and Psychotherapy - Hannover Medical School, Germany
- Visiting Professor (2012-2015) Harvard Medical School, MA, USA



Advisor





Chris Pittenger, MD, PhD, FAPA, FANA

Yale University School of Medicine

- · Professor of Psychiatry
- Assistant Chair for Translational Research, Psychiatry
- Director, Yale OCD Research Clinic
- Director, Neuroscience Research Training Program, Yale Department of Psychiatry



Emmanuelle Schindler, MD, PhD

Yale University School of Medicine

- Assistant Professor of Neurology, Yale School of Medicine
- · Medical Director, Headache Center of Excellence, VA Connecticut Healthcare System



**Bob Wold** Cluster Busters

- Founder and President Clusterbusters, Inc.
- Board of Directors AHDA (Alliance for Headache Disorder Advocacy)





William Young, MD

Jefferson University Hospital

- Professor of Neurology and Co-Director Inpatient Program, Jefferson University Hospital
- Founder, Physician & Advisor Coalition for Headache and Migraine Patients (CHAMP)









# Ceruvia Lifesciences represents a unique opportunity to make a significant impact

We believe patients suffering from debilitating headache disorders and difficult-to-treat psychiatric disorders, like OCD, no longer have to live this way.

#### **PROMISING**

Promising real-world and clinical data support a truly differentiated efficacy profile with good safety and tolerability

#### **DIFFERENTIATED**

All compounds in the portfolio have the potential to be clearly differentiated from current standard of care in conditions with significant unmet needs

#### **SUPPORTED**

Modes of action support efficacy in other indications for product life-cycle management

#### **SIGNIFICANT**

Significant unmet needs with a substantial disease burden means significant benefit can be brought to patients

#### **REWARDING**

Robust data and going concern status support commercial returns





Transformational Medicines for Neurological & Psychiatric Disorders

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