

Developing Abuse-Deterrent Medications to Reduce the Potential for Harm

A PROBLEM HAS CREATED AN UNADDRESSED MARKET

### PRESCRIPTION STIMULANT ABUSE IS A LARGE, GROWING CONCERN

5+ Million

Americans misuse ADHD prescription stimulants annually

From 2004 - 2011, emergency department visits due to non-medical use of stimulants<sup>2</sup>

Increased 4.7x

From 2010 - 2017, deaths associated with prescription stimulants<sup>3</sup>

**Increased 5x** 

1: SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2018 / 2: Drug Abuse Warning Network, 2011 / 3: Black, CPDD, 2020

### Investment Opportunity



#### Lead product, ADAIR, targeting NDA filing in <18 Months



Expected to be the first immediate-release (IR) and abuse-deterrent formulation (ADF) of dextroamphetamine (Adderall®)



Leveraging de-risked 505(b)(2) regulatory pathway



Developing platform for other abuse-deterrent products (e.g. Ritalin®)



Partnered with the #1 ADHD Company in Europe

#### **LOW RISK**

Patented formulation of a drug that has been approved and used clinically for over 50 years

#### **LOW COST**

~\$15 million spend to fund through NDA filing

## STRONG COMMERCIAL POTENTIAL

Targeting \$9 billion/yr U.S. ADHD market<sup>1</sup>

1: IQVIA, NSP, 2019

#### Pipeline

Program	Indication	Formulation	Pre-Clinical	Clinical	NDA Submission	Next Planned Milestone
Abuse-Deterrent Destroamphelamine IR	ADHD	★ 505(b)(2) re	gulatory pathway			Single pivotal Intranasal Abuse Study: 2H 2021
Abuse-Deterrent Destroamphetamine R	Narcolepsy	★ 505(b)(2) re	gulatory pathway			Target NDA Submission: Q2 2022
ADAR Abuse-Dieter unt Destroamphetamine R	ADHD	Europe				Regulatory Scientific Advice: 2021
ADMR Abuse-Deterrent Destroamphelamine R	ADHD					Open IND: 2H 2021

★ ADAIR is being developed using the 505(b)(2) regulatory pathway; only one additional clinical study, a pivotal intranasal abuse study is expected to be required before filing the NDA in Q2 2022.

NDA filing for ADAIR expected to cover both ADHD and Narcolepsy indications.

#### ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD)

# A LARGE AND GROWING MARKET

15+ Million

people in the US are estimated to have ADHD<sup>1</sup>

2019 Total ADHD Sales in the US<sup>2</sup>

~\$9 Billion

\$2.5 Billion

Sales of the only FDA-approved drug with abuse-deterrent properties - Vyvanse<sup>3</sup>

1: CDC; Kessler, 2006; US Census, 2020 / 2: IQVIA, NSP, 2019 / 3: Takeda, 2019 annual report

## Platform Technology Designed to Deter Abuse







Deters intranasal and intravenous/injection abuse



Active ingredient is embedded in a semi-solid, waxy paste inside a gelatin capsule



Technology can be applied to other Rx drugs with abuse potential, e.g., Ritalin<sup>®</sup>







Cutting open an ADAIR, abuse-deterrent capsule reveals a paste-like substance

\*ADAIR is an investigational drug and is not approved by the FDA

## Planned ADAIR Development Timeline Toward NDA Filing

FDA-confirmed 505(b)(2) development path / No Phase 2 or Phase 3 clinical efficacy studies are required

