

# JUNE 2023

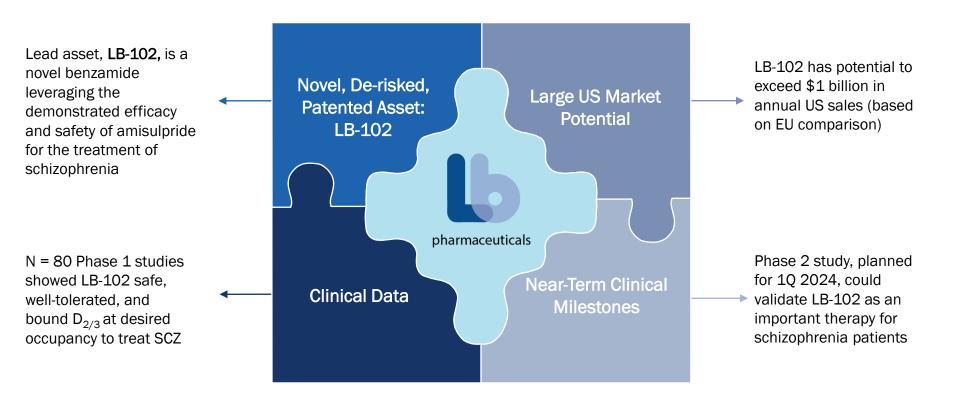
Making Smart Chemical Changes to Create Improved
Novel Therapeutics

# **DISCLAIMERS**

The Company has made statements throughout this presentation which constitute forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause its actual results, levels of activity, performance or achievements to be materially different from any results, levels of activity, performance or achievements expressed or implied by any such forward-looking statements. In some cases you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expect," "hopes," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "likely," "potential," or "continue" or the negative of these terms and similar words. Although management believe that the expectations reflected in these forward-looking statements are reasonable, management cannot guarantee future results, levels of activity, performance or achievements. Furthermore, management undertakes no obligation to update any forward-looking statements for any reason unless required to do so by law.

# LB PHARMACEUTICALS INVESTMENT HIGHLIGHTS

CNS-focused biotech building a pipeline of potential best-in-class therapies for the US market



# LB PHARMACEUTICALS BUSINESS STRATEGY

- CNS-focused development stage company intent on building a pipeline of improved versions of effective drugs that are commercially unavailable in the US
- Lead asset LB-102 is a methylated version of amisulpride, one of the leading antipsychotics in use worldwide for the treatment of schizophrenia
  - LB-102 was designed to be effective at lower doses than amisulpride, which could improve safety and tolerability
  - LB-102 is a novel chemical structure with composition of matter patents issued in the US and abroad
  - Even if clinically equivalent to amisulpride, LB-102 would be one of the most effective antipsychotics on the US market with IP until at least 2037 and potential to yield \$1 billion in annual sales based on ex-US market data\*
- First-in-class team of executives, board members, and advisors with extensive experience in drug development in the psychiatric arena

# **MANAGEMENT TEAM**

### Zachary Prensky, Chief Executive Officer & Co-Founder

- Managed family office from 1997-2015
- Portfolio responsibilities included oversight of all biotechnology investments

### Anna Eramo, M.D., Chief Medical Officer

- Former Clinical and Medical Affairs head at Lundbeck
- Has 18 years of global CNS experience; oversaw US development of brexpiprazole
- Trained clinical psychiatrist

### Andrew Vaino, Ph.D., Chief Science Officer

- Chemistry PhD from Queen's University with two decades experience in biotech
- MBA from UC Irvine
- Inventor of two molecules studied clinically

### Marc Panoff, Chief Financial Officer

- Previously CFO of Retrophin raised \$150 million in equity and debt financings and uplisted company to Nasdaq Global Market
- Previously CFO of Neurologix and Nephros

### **BOARD OF DIRECTORS**

#### Zachary Prensky, CEO and Co-Founder

### Robert Ruffolo, Ph.D., D.Sc. (h), D.Eng. (h), F.C.P.P.

- Former President of R&D, Wyeth Pharmaceuticals
- Previously SVP and Director, Biological Sciences, Worldwide,
   SmithKline Beecham Pharmaceuticals (now GlaxoSmithKline)

#### Piero Poli

 Owner and CEO of Rivopharm SA, a Swiss company that has developed over 25 molecules and registered generic products throughout Europe, including amisulpride

#### Vincent Grattan, R.Ph

- Co-Founder and senior consultant
- PA registered pharmacist currently employed by MHM Services, responsible for all facets of drug utilization management collaborating with a team of 300+ clinicians; 20 years of psychopharmacology experience

### Edmund Sullivan, Founding Investor

Formerly at Citigroup and Cowen & Company

### SCIENTIFIC ADVISORS

#### John M. Kane, M.D., Chairman

 Vice President, Behavioral Health Sciences, Northwell Health; Chairman of Psychiatry, Zucker Hillside Institute

### Christoph Correll, M.D.

 Medical Director, Recognition and Prevention Program, The Zucker Hillside Hospital; Professor, Center for Psychiatric Neuroscience, The Feinstein Institute for Medical Research

#### Stefan Leucht, M.D.

Department of Psychiatry and Psychotherapy,
 Technische Universitat Munchen, Munich, Germany

#### Ira Glick, M.D.

Professor of Psychiatry and Behavioral Sciences,
 Stanford University School of Medicine

#### Herbert Meltzer, M.D.

Professor of Psychiatry & Behavioral Sciences,
 Pharmacology and Physiology, Northwestern
 University

# LB PHARMACEUTICALS - FINANCING HISTORY

Financing Round	Date(s)	Gross Amount Raised	Milestones Achieved
Seed Rounds	2015 - '17	\$1.9M	LB-102 Invention and <i>in-vitro</i> studies  3 animal SCZ pre-clinical studies  Initial CMC Formulation
Series A	2017 - '18	\$8.4M	Completion of all IND-enabling studies  Successful Phase 1 clinical trial in 64 healthy volunteers  Successful completion of Phase 1 trial (safety/PK) in 64 healthy volunteers
Convertible Notes	2020	\$10.0M	Successful Phase 1b PET imaging study (dopamine receptor occupancy) in 16 healthy volunteers  Successful completion of two long-term toxicity studies in dogs and rats  Production of LB-102 tablet for Phase 2 drug product  Phase 2 clinical trial preparation; CMO hire, CRO engagement, site selection
Warrant Holder Rights Offering	2022	\$0.9M	Working Capital
Convertible Notes	2022/2023	\$25.7M	Expected to be used in conjunction with a Series B financing to conduct a first in patient Phase 2 clinical trial of LB-102
Totals		\$46.9M	LB-102 Phase 2 Ready

# **SCHIZOPHRENIA**

- Schizophrenia (SCZ) is a chronic and debilitating disease affecting approximately 1% of the US population<sup>1</sup>
  - 100,000 new SCZ patients diagnosed per year<sup>2</sup>
  - SCZ patients have profoundly diminished quality of life
    - Fewer than 20% hold full-time employment;<sup>3</sup> increased odds of arrest<sup>1</sup>
  - Life expectancy of SCZ patients is reduced by 10-20 years compared to the general population<sup>4</sup>
    - Approximately 5% SCZ patients die of suicide<sup>5</sup>
  - Disease defined by three major groups of symptoms
    - Positive symptoms: delusions, hallucinations, agitation
    - Negative symptoms: lack of social engagement, depression
    - Cognitive symptoms: memory deficits, impaired executive functions

<sup>1</sup> About Schizophrenia - Schizophrenia & Psychosis Action Alliance (sczaction.org)

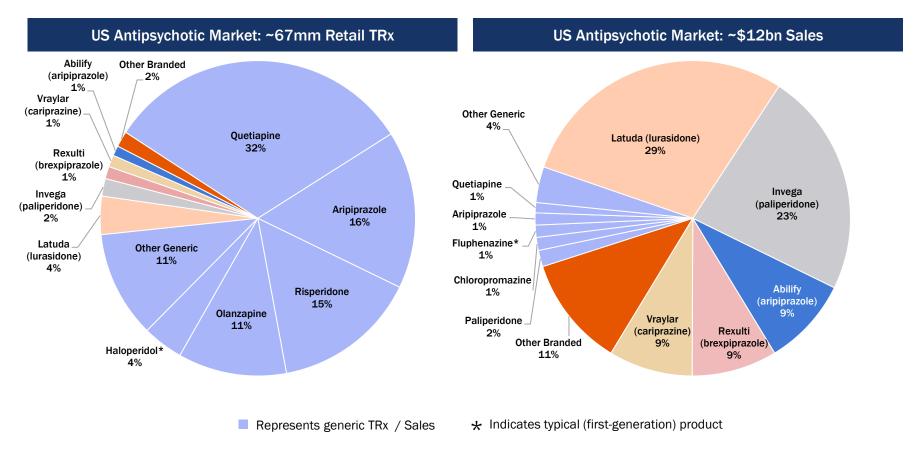
<sup>2 &</sup>lt;u>Schizophrenia Symptoms, Patterns and Statistics and Patterns (mentalhelp.net)</u>

<sup>3</sup> The Atlantic, "Job Hunting with Schizophrenia", Maria Hengeveld, July 28, 2015

<sup>4</sup> Moradi et al. 2018

<sup>5</sup> Palmer et al. 2005

# US ANTIPSYCHOTIC MARKET LANDSCAPE(1)



- Branded antipsychotic drugs generate ~\$11 billion in sales annually in the US
- Despite limited efficacy, and a crowded generic market, new branded antipsychotics such as Latuda, Vraylar, and Rexulti are approaching or have achieved > \$1 billion each in annual sales in the US

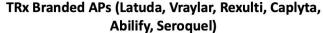
# SCHIZOPHRENIA – UNMET MEDICAL NEED

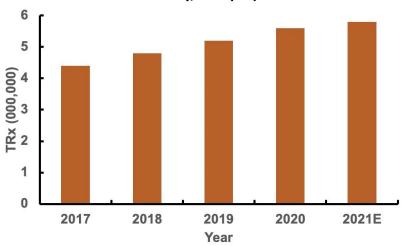
- Despite 20+ FDA approved drugs, SCZ patients don't get adequate help
  - An estimated 50% of patients with SCZ do not take their prescribed medications as directed<sup>1</sup>
  - Up to 75% of SCZ patients cycle through multiple drugs within 18 months, with up to 60% failing to find an effective therapy<sup>2</sup>

Standard of care treatments do not adequately treat a heterogeneous patient population; alternative novel treatments are badly needed

### **Branded Rx growing**

Phase 2 data price catalyst<sup>3</sup>





### Share Price Pre/Post P2 SCZ Data

	Phase 2	PANNS A	Share Price	Mkt Cap
Company	<b>Announcement</b>	From BL	Increase	Increase (\$B)
KRTX	11/18/19	-17.4	5.5x	2
CERE	6/29/21	-19.5*	2.4x	2.2

<sup>\* 30</sup> mg QD

<sup>1</sup> About Schizophrenia - Schizophrenia & Psychosis Action Alliance (sczaction.org)

<sup>2</sup> Lieberman JA, et al. Effectiveness of antipsychotic drugs in patients with chronic schizophrenia. N Engl J Med. 2005;353:1209-1223.

<sup>3</sup> Shows percentage change of closing share price and market capitalization for two companies upon annoucement of successful Phase 2 clinical studies for schizophrenia during 2019-2021. Source: NASDAQ.

### AMISULPRIDE BACKGROUND

- Amisulpride is a benzamide indicated for the treatment of schizophrenia in Europe since 1986
  - Patented and developed by Synthélabo (acquired by Sanofi)
  - Selective  $D_2(K_i = 2.8 \text{ nM})/D_3(K_i = 3.2 \text{ nM})$  and  $5HT_7(K_i = 31 \text{ nM})$  antagonist
  - In July 2000 Sanofi announced it would discontinue development of amisulpride in the US based on IP
- Amisulpride has generated over 2.5 million prescriptions annually for the past three years in Europe
- 35 years of clinical use demonstrates an excellent efficacy/safety profile

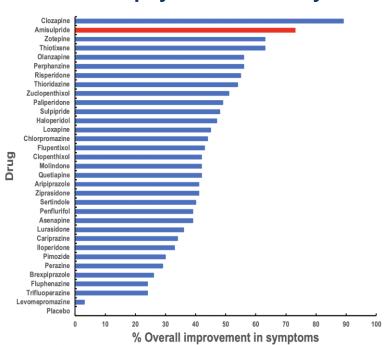
# AMISULPRIDE COMPARATIVE EFFICACY/SAFETY

Meta-Analysis of 32 Schizophrenia (SCZ)

Drugs<sup>(1)</sup>

(n = 53,500)

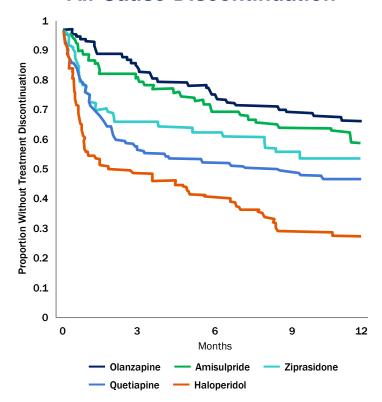
### **Antipsychotic Efficacy**



Amisulpride is one of the most effective antipsychotics in the world

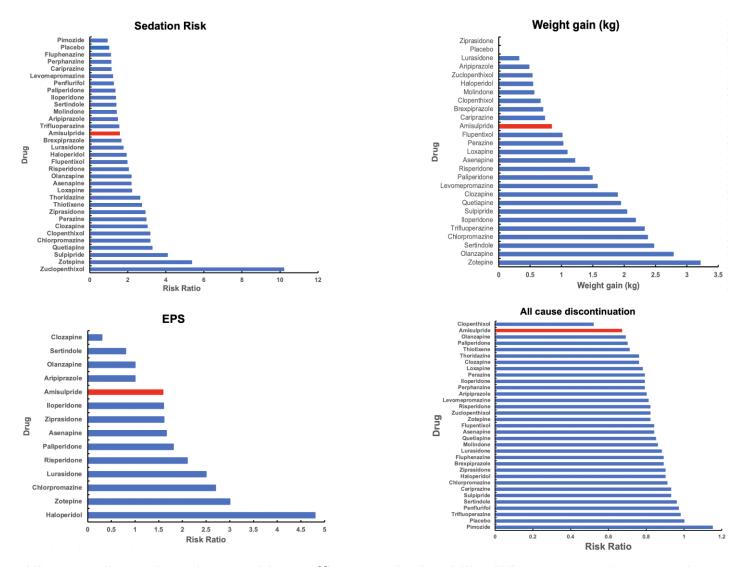
EUFEST Study<sup>(2)</sup>
(Clinical Trial of 5 SCZ Drugs in First Episode)
(n = 498)

### **All-Cause Discontinuation**



Amisulpride is one of the best tolerated antipsychotics

### AMISULPRIDE COMPARATIVE SAFETY



• All cause discontinuation combines efficacy and tolerability. When reported separately, more patients dropped out due to inefficacy (40%) than due to adverse events (20%)

# LB-102 OVERVIEW

LB-102 is a methylated version of amisulpride

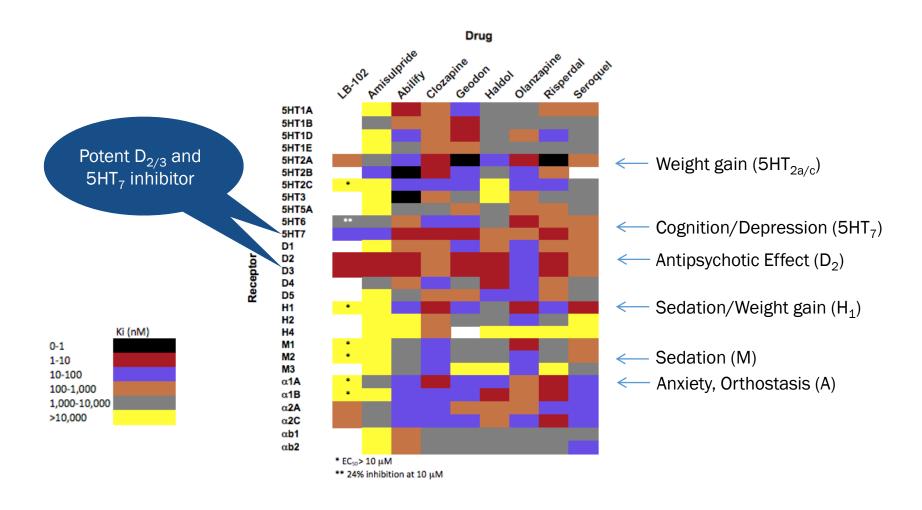
Amisulpride (1983)

LB-102 (2016)

- Novel chemical structure with chemical properties designed to improve amisulpride's efficacy and safety
- Safe and well-tolerated in two (n = 80) Phase 1 clinical studies
- Three US and four ex-US composition of matter patents covering LB-102 issued extending to at least 2037
- CNS receptor binding profile similar to amisulpride: high selectivity for  $D_{2/3}$  and  $5HT_7$
- LB-102 same as/better than amisulpride in preclinical animal models of SCZ

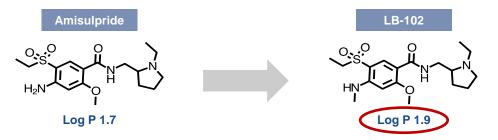
### LB-102 AND AMISULPRIDE RECEPTOR SPECIFICITY

LB-102 is a selective  $D_2/D_3/5HT_7$  antagonist with minimal off-target activity

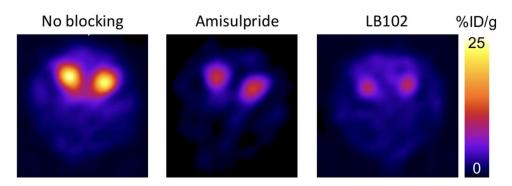


### LB-102: ENHANCING AMISULPRIDE'S PRODUCT PROFILE

- Of 30 psychiatric medications tested amisulpride was least able to passively diffuse across model BBB<sup>(1)</sup>
- Improving BBB permeability could improve efficacy/decrease adverse events
- Methylation has been shown to improve membrane permeability without changing receptor binding activity, for example desipramine to imipramine and nortriptyline to amitriptyline



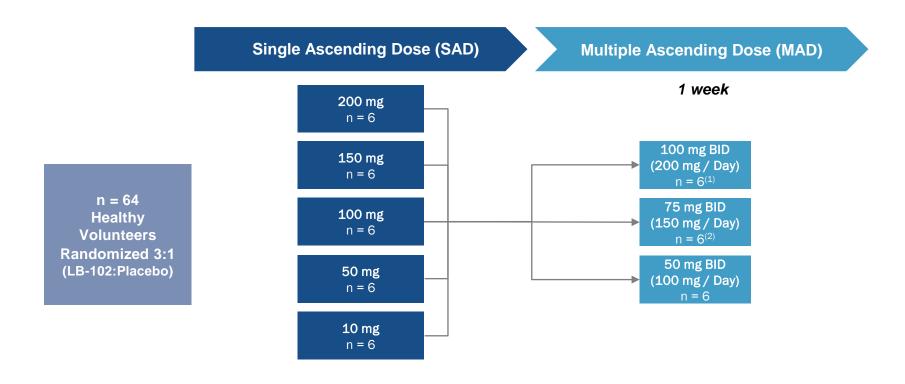
In a PET study, using  $^{11}$ C raclopride, directly measuring dopamine RO in mice the same dose of LB-102 showed LB-102 bound D<sub>2/3</sub> receptors ~2X as strongly as amisulpride (K<sub>i</sub>s are similar)



PET scans taken 140 min after dosing either 100 mg/kg amisulpride or LB-102

# LB-102 PHASE 1 CLINICAL TRIAL OVERVIEW

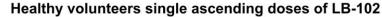
- Dosing: 5 single ascending dose (SAD) cohorts/3 multiple ascending dose (MAD, 1 week, BID dosing) cohorts
- Endpoints: Safety and pharmacokinetics
- Single Site: Medpace in Cincinnati, OH

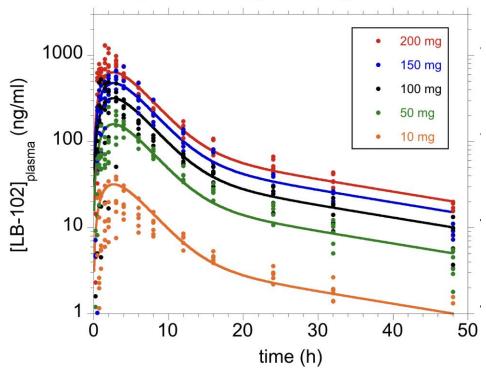


# LB-102 PHASE 1 PHARMACOKINETICS (SAD)

LB-102 exhibits favorable PK properties, with a half-life of 12+ hours and Tmax of 2-3 hours

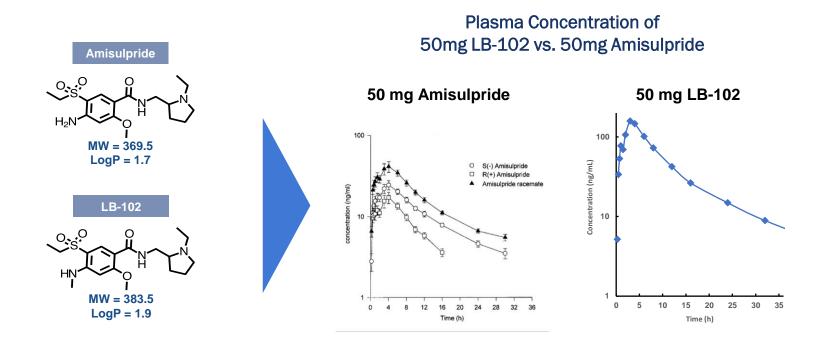
Dose LB-102 (mg)	Cmax (ng/mL)	AUCinf (h*ng/mL)	Tmax (h)	T <sub>1/2</sub> (h)
10	24	253	3	13.7
50	176	1600	3	12.3
100	349	2823	2.8	14.7
150	596.5	4650	3.2	12.6
200	976	7001	2	12.8





# PLASMA EXPOSURE OF LB-102 > AMISULPRIDE

Rosenzweig<sup>(1)</sup> reported PK data on 18 healthy volunteers exposed to a single dose 50 mg amisulpride



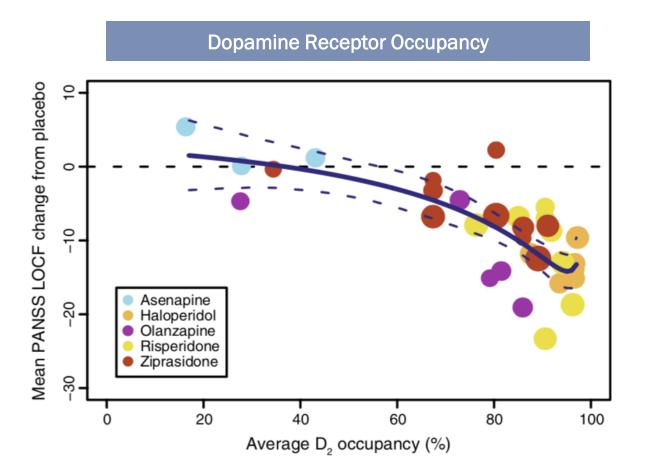
Observed LB-102 plasma exposure is ~ 2.5x that of amisulpride<sup>(2)</sup>

# LB-102 PHASE 1 ADVERSE EVENTS

	Si	ngle ascending	dose				Multiple as	cending dos	se
Adverse event	Placebo	10 mg	50 mg	100 mg	150 mg	200 mg	50 mg BID	75 mg BID	100 mg BID
n	16	6	6	6	6	6	6	6	6
Elevated prolactin		2	3	1	1	1	2	2	1
Diarrhea			1						
Upper respiratory infection			1	1					
Abdominal pain	1	1		1					
Nausea						1		1	1
Urticaria				1					
Acute dystonia						1		1	2
QT prolongation						1			
Insomnia						1		1	
Gastroesophageal reflux						1			
Headache	1					1			
Oropharyngeal pain						1			
Heart palpitations						1			
Vomiting									1
Dry mouth									1
Somnolence								1	1
Dizziness								1	
Migraine								1	
Back pain	1							1	
Bug bite	1								
Total AEs	4	3	5	4	1	9	2	9	7

- Prolactin elevation (PRL), which was reversible and unassociated with clinical consequences, was observed at all doses, a consequence of dopamine receptor binding
- Dosing in 200 mg/d MAD cohort was stopped after 3 days due to two occurrences of EPS (acute dystonia)
  - EPS associated with excess  $D_{2/3}$  RO, suggesting need to tamp down dose < 200 mg/d

### DOPAMINE RO DIRECTLY LINKED TO IMPROVEMENTS IN SCZ PATIENTS

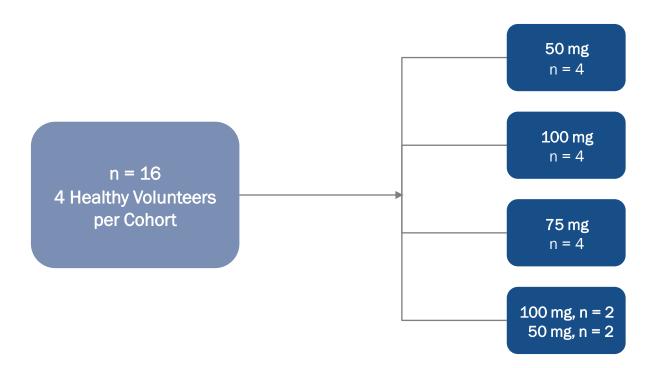


Dopamine RO a good predictor of PANSS improvement<sup>(1)</sup>

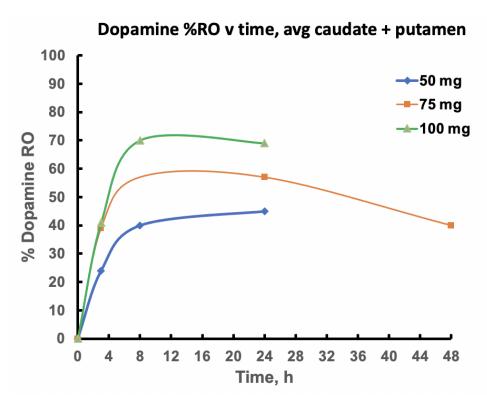
Notes: (1) Source: The AAPS Journal, **2011**, 13, 121-130

# LB-102 PHASE 1b PET IMAGING STUDY (NCT04588129)

- Dosing: Adaptive design with 4 cohorts of 4 healthy volunteers each
  - Multiple PET scans per subject using <sup>11</sup>C raclopride as tracer
- Study Objectives: To confirm  $D_2/D_3$  target engagement and inform Phase 2 dosing

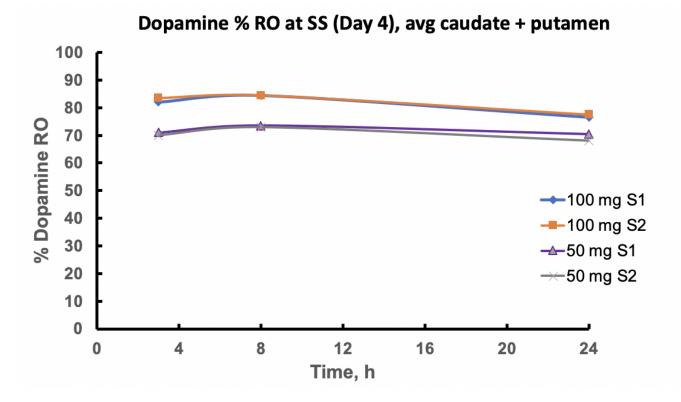


# PHASE 1b - COHORTS 1 - 3, SINGLE DOSE



- Subjects in Cohorts 1 (100 mg) and 2 (50 mg) were scanned at 2.5, 7.5, and 23.5 hrs post-dose
- Subjects in Cohort 3 (75 mg) were scanned at 2.5, 23.5, and 47.5 hrs post-dose
- Desired dopamine RO between 60% and 75%
- Data suggests that LB-102 can be dosed once a day

# PHASE 1b - COHORT 4, STEADY STATE, 100 MG (N=2); 50 MG (N=2)



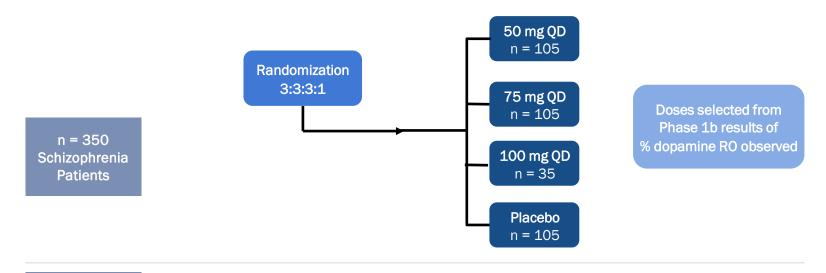
- Subjects scanned 2.5, 7.5, and 23.5 hrs after 4 days QD dosing
  - Dopamine RO observed at 50 mg was in the desired range for an effective schizophrenia drug
  - 50 mg LB-102 afforded same dopamine RO as 400+ mg amisulpride per day

### PHASE 1b - KEY TAKEAWAYS

- No reported SAEs or EPS
- Dopamine receptor occupancy in desired range at 50 mg to 100 mg dose
- Confirms hypothesis from Phase 1 study
- Planned dosing for Phase 2 study: 50 mg, 75 mg, and 100mg once per day
  - FDA guided LB-102 could be dosed up to 200 mg/d in SCZ patients
  - Therapeutic doses expected to be well within the margin of safety

# LB-102 PHASE 2 CLINICAL PROGRAM

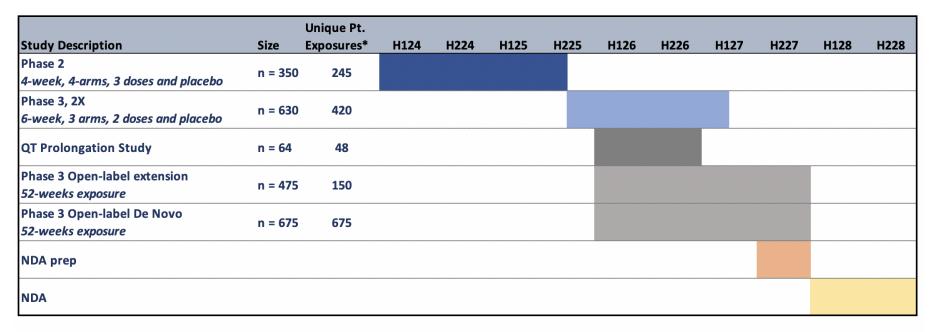
- Trial Size: Expecting to enroll ~350 SCZ patients at ~25 sites
- Design: 3 doses LB-102 versus placebo (4 weeks duration, in-patient, double-blind, placebo controlled)
- Primary Endpoint: Change in PANSS
- Development plan will follow well-established criteria for FDA approval of a schizophrenia drug (cf. Rexulti, Vraylar, Latuda)
  - LB-102 Phase 2 study designed to potentially be registrational study



Inclusion Criteria

Adults, 18 to 50 years old, diagnosed with acute schizophrenia

# LB-102 CLINICAL DEVELOPMENT PROJECTED TIMELINE



<sup>\*</sup> Does not include 48 healthy volunteers exposed to LB-102

- Start of Phase 2 study dependent on close of Series C financing
- CMC activities to support Phase 2 study are completed

# LB-102 KEY DIFFERENTIATORS

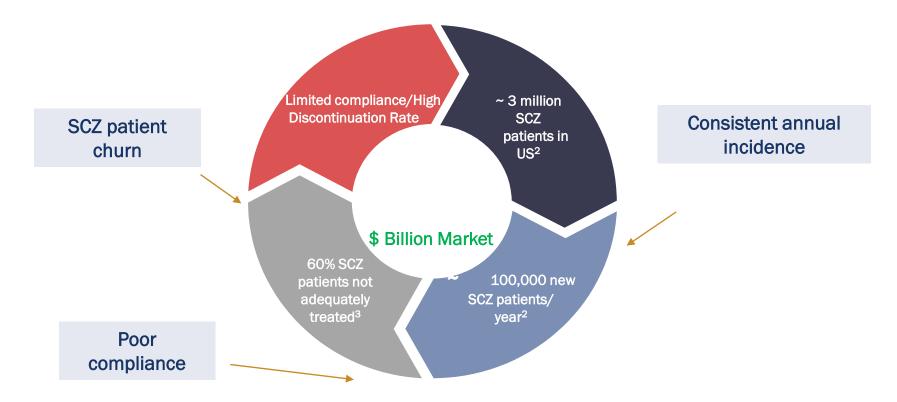
 Superior efficacy than most recently launched antipsychotics and other compounds in development

	Avg PANSS ∆ from BL <sup>1</sup>
Caplyta	-14.1
Caplyta Rexulti, 4 mg	-19.9
Vraylar, 3 mg Amisulpride	-22.4
Amisulpride	-28.9

- Minimal off-receptor binding ( $D_2$ ,  $D_3$ ,  $SHT_7$ ) potentially leading to low incidence of AEs
- Potential use in patients with predominantly negative symptoms, bipolar depression, depression, and Alzheimer's psychosis
  - Amisulpride one of two drugs to show statistically significant improvement in negative symptoms (SANS  $\Delta$  12 points vs. placebo)<sup>2</sup>
  - Equivalent to Prozac in clinical study of depression<sup>3</sup>
  - ATLAS study showed amisulpride effective in treating psychosis in elderly<sup>4</sup>
- Weakly metabolized, low risk of drug/drug interactions
- LB-102's low expected therapeutic doses (50 mg LB-102 = same dopamine RO as 400 mg amisulpride) could be amenable to LAI formulation

# **LB-102 US MARKET OPPORTUNITY**

- Amisulpride/LB-102 differentiated by robust efficacy for both positive and negative symptoms of the disease and a clean AE profile
  - Prescriptions in the Europe exceed 2.5 million/year<sup>1</sup> despite a lack of sales/marketing support for 15 years
- Branded antipsychotic drugs generate ~\$11 billion in sales annually in US



LB-102 combines de-risked efficacy/safety of amisulpride with IP of a NCE

# PIPELINE EXPANSION POTENTIAL

LB-102 has the potential for clinical impact in areas outside of schizophrenia, such as depression

LB-102 (schizophrenia)		
LB-102 (depression)		
LB-102 (schizophrenia – negative symptoms)		
LB-102 (schizophrenia - LAI)		
LB-102 (bipolar depression)		

### SCHIZOPHRENIA ASSETS FROM SELECT PUBLIC COMPANIES

Drug	Company (Ticker)	Δ PANSS from BL	Potential Other Indications	Post Phase 2 Market Cap <sup>11</sup>
Caplyta®	Intra-Cellular Therapies (ITCI)	-15.6 (42 mg) <sup>1</sup>	Bipolar depression (approved) <sup>2</sup> Major depressive disorder <sup>3</sup>	\$421M
Emraclidine	Cerevel Therapeutics (CERE)	-19.5 (30 mg) <sup>4</sup>		N/A <sup>5</sup>
KarXT	Karuna Therapeutics (KRTX)	-21.2 <sup>6</sup>	Psychosis in Alzheimer's disease <sup>7</sup> Negative symptoms of SCZ <sup>6</sup>	\$2.7B <sup>13</sup>
Brilaroxazine	Reviva Pharmaceuticals (RVPH)	-20.0 <sup>8</sup>	Bipolar disorder, Major depressive disorder, Attention deficit hyperactivity disorder, Pulmonary Arterial Hypertension, Idiopathic Pulmonary Fibrosis <sup>9</sup>	\$80.3M
Amisulpride (LB- 102 analog)	LB Pharmaceuticals	-28.9 <sup>10</sup>	Approved to treat dysthymia (low-grade depression) in 4 countries <sup>11</sup>	N/A

**Note:** The data provided in the table above is for informational purposes only and may not directly correlate to the valuation of the Company or LB-102. Neither the Company nor Maxim Group can guarantee that the Company will successfully complete its planned Phase 2 study or that the Company's valuation will be positively impacted by a successful Phase 2. For a number of reasons, many of which are outside of the Company's control, the Company's valuation following a successful Phase 2 could vary materially from the valuations presented above. **Investors should carefully read the risk factors listed on the next slide, 33, and the section of the PPM titled "Risk Factors" for a discussion of the risks that the Company faces in commercializing and marketing LB-102.** 

<sup>&</sup>lt;sup>1</sup> JAMA Psychiatry, **2020**, 77, 349-358

<sup>&</sup>lt;sup>2</sup>ITCl press release Intra-Cellular Therapies Announces U.S. FDA Approval of CAPLYTA® (lumateperone) for the Treatment of Bipolar Depression in Adults | Intra-Cellular Therapies Inc. (intracellulartherapies.com), 12/20/21

<sup>&</sup>lt;sup>3</sup> ITCI pipeline webpage <u>Lumateperone and Follow-On Compounds</u> | Intracellular Therapies, accessed 9/14/22

<sup>&</sup>lt;sup>4</sup> CERE press release Cerevel Therapeutics Announces Positive Topline Results for CVL-231 in Phase 1b Clinical Trial in Patients with Schizophrenia | Cerevel Therapeutics, 6/29/21

<sup>&</sup>lt;sup>5</sup> CERE currently enrolling patients in Phase 2 for schizophrenia and their pipeline contains other drug candidates for other disease areas/indications. Current market cap is \$4.5B as of 9/15/2022

<sup>&</sup>lt;sup>6</sup> KRTX press release Karuna Therapeutics Announces Positive Results from Phase 3 EMERGENT-2 Trial of KarXT in Schizophrenia | Karuna Therapeutics (karunatx.com), 8/8/22

<sup>&</sup>lt;sup>7</sup>KRTX pipeline webpage Pipeline & Programs • Karuna (karunatx.com), accessed 9/14/22

<sup>8</sup> RVPH press release Reviva Announces Full Details of Positive Phase 2 Clinical Trial Results for Acute Schizophrenia | Reviva Pharmaceuticals, 4/26/21

<sup>&</sup>lt;sup>9</sup> RVPH pipeline webpage Reviva Pharmaceuticals | Product Pipeline, accessed 9/14/22

<sup>&</sup>lt;sup>10</sup> Neuropsychopharmacology, **2002**, 27, 1071 and Current Medical Research and Opinion, **2002**, 18, 355

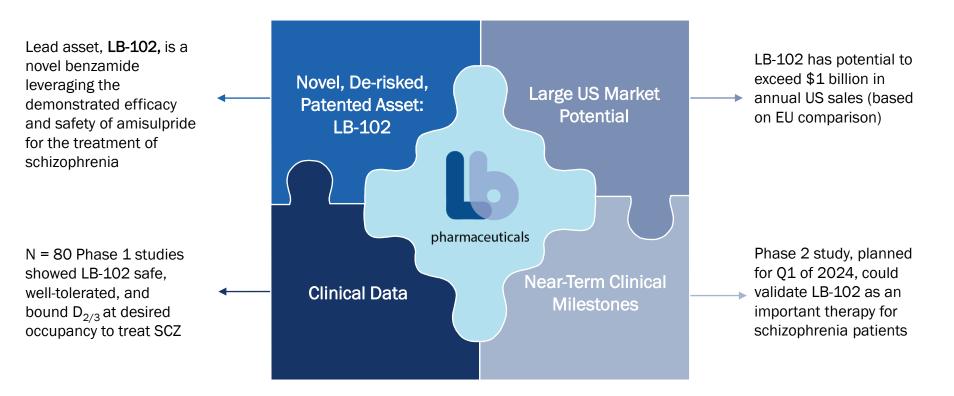
<sup>&</sup>lt;sup>11</sup> Brazil, Italy, Latvia, Slovakia, IMS report 2015

<sup>12</sup> Market capitalization valuations at the time of exchange closing on the date that Phase 2 study data was announced. Source: NASDAQ.

<sup>&</sup>lt;sup>13</sup> In August 2022, KRTX announced the topline results from its Phase 3 Emergent-2 trial of KarXT in adults with schizophrenia. The change in PANSS from baseline in this study was -21.2. The market capitalization increased to approximately \$7.2B upon the closing price of KRTX stock on date of the announcement.

# LB PHARMACEUTICALS INVESTMENT HIGHLIGHTS

CNS-focused biotech building a pipeline of potential best-in-class therapies for the US market





# THANK YOU