LB Pharmaceuticals Inc

Developing Novel Therapies for Neuropsychiatric Disorders

November 2025

pharmaceuticals

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LB Pharma is Building a Fully Integrated CNS-focused Company

De-Risked Approach with Late-stage Trials Planned in Schizophrenia (SCZ) and Bipolar depression (BPD)

Positive Phase 2 Data Highlights Potential for Differentiated Profile in $12B Branded AP Market[1]

Streamlined Path to Approval in SCZ with a Single Phase 3 Trial Based on Positive FDA Feedback

Compelling Expansion Opportunities with Strong Scientific and Clinical Rationale, Life Cycle Management

Robust IP Portfolio with Issued Composition of Matter (COM) Protection Through 2041[2]

Strong Balance Sheet from Recent IPO that Supports Multiple Clinical Read-outs

[1] AP = antipsychotic; 2024 sales data from EvaluatePharma; [2] Includes estimated Hatch-Waxman extension, composition of matter IP expires 2037; LB-102 patent portfolio includes: 7 U.S. issued, 11 foreign issued, 7 U.S. pending, and 19 foreign pending patents

Developing Differentiated Assets with Late-Stage Trials in Two Indications

Compelling commercial profile expected in both schizophrenia and bipolar depression

Clinically meaningful, competitive efficacy on par with or better than approved agents

Validated mechanism with simple dosing profile: once daily (QD), no food effect, few drug-drug interactions

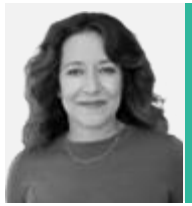
Potentially class-leading safety profile with limited sedation and low rates of extrapyramidal symptoms (EPS)

First-in-class benzamide in the U.S. for the treatment of neuropsychiatric disorders

Robust effect on cognition, negative symptoms and potentially anhedonia, key unmet needs in CNS diseases

Global first-in-class benzamide long-acting injectable (LAI) formulation in development

World-Class Leadership Backed by Premier KOLs and Investors



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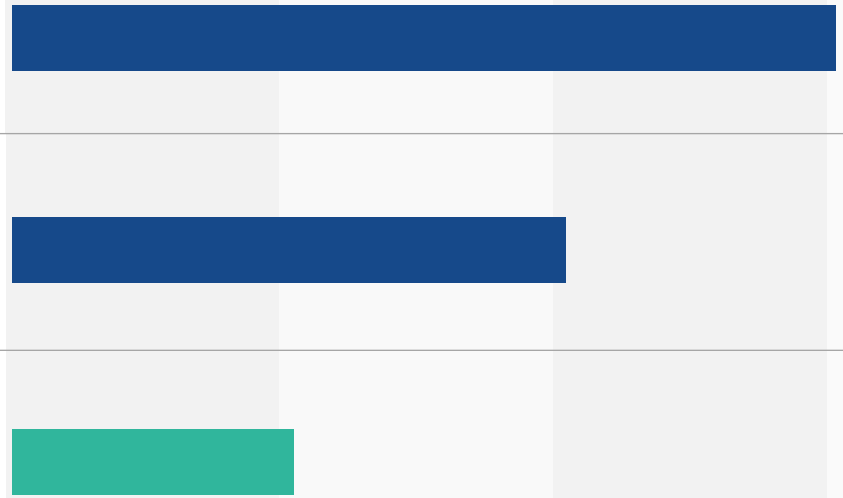
Significant Upcoming Milestones with Runway Expected into 2Q 2028

		Preclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
LB-102 (Oral)	Acute Schizophrenia					**Topline data expected 2H 2027** **Pre-NDA meeting expected 1Q 2028**
	Bipolar I Depression					**Topline data expected 1Q 2028**
LB-102 (LAI)	LAI Formulation					**Formulation development in 2026**



LB-102 is a Derivative of Amisulpride, a Successful and Widely Used AP in Europe

Advantages of Amisulpride

Approved for use in SCZ, negative symptoms of SCZ and dysthymia, a form of depression[1]

More than 2 million monthly Rx / yr in EU[2]

Selectively inhibits D2, D3, and 5HT7 with few off target effects[3]

Second highest effect size (0.73) among approved APs[4]

Favorable safety and tolerability profile with one of the lowest all-cause discontinuation rates[4,5]

Extensive use in mood disorders (BPD and MDD)

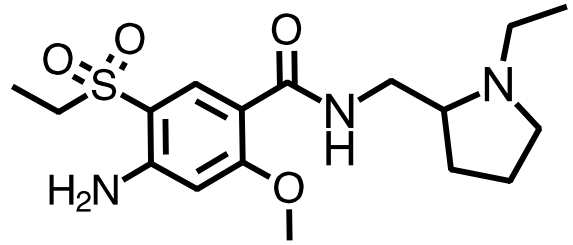
Limitations of Amisulpride

Poor blood-brain barrier (BBB) penetration

Requires high doses for SCZ (400-800 mg)

Twice daily (BID) dosing

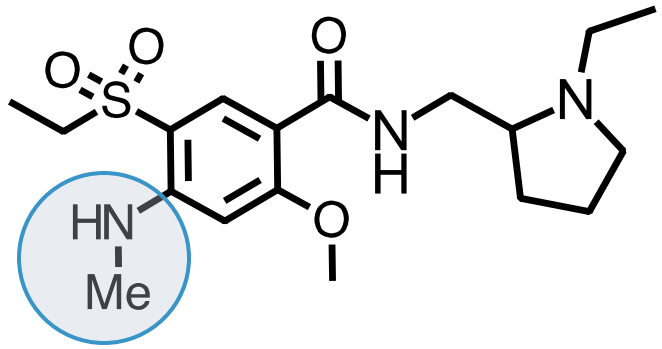
Amisulpride



[1] Solian label; [2] Proprietary Company data from Germany, Italy, Spain, France, and 12 other continental European countries, Rx / year = prescriptions per year; [3] Psychopharmacology (Berl). 2009 July 205(1): 119; [4] The Lancet. 2019;394(10209):939–949; [5] Lancet, 2008, 371, 1085-1097;

LB-102 Was Purpose-Built to Address Amisulpride's Limitations

Designed to improve BBB penetration of amisulpride



LB-102

Methylation of amisulpride improved lipophilicity, enabling more efficient transport across the BBB and longer residence time in the CNS[1]

Advantages of LB-102 versus amisulpride

- Improved potency, lowering required dose and reducing systemic exposure – 50 mg LB-102 ≈ 400 mg amisulpride[1]
- Enabled convenient once-daily dosing
- Supported new chemical entity status and COM IP
- Potential for improved tolerability (e.g., lower EPS) validated by Phase 2 clinical experience
- Retained CNS receptor binding profile[2]

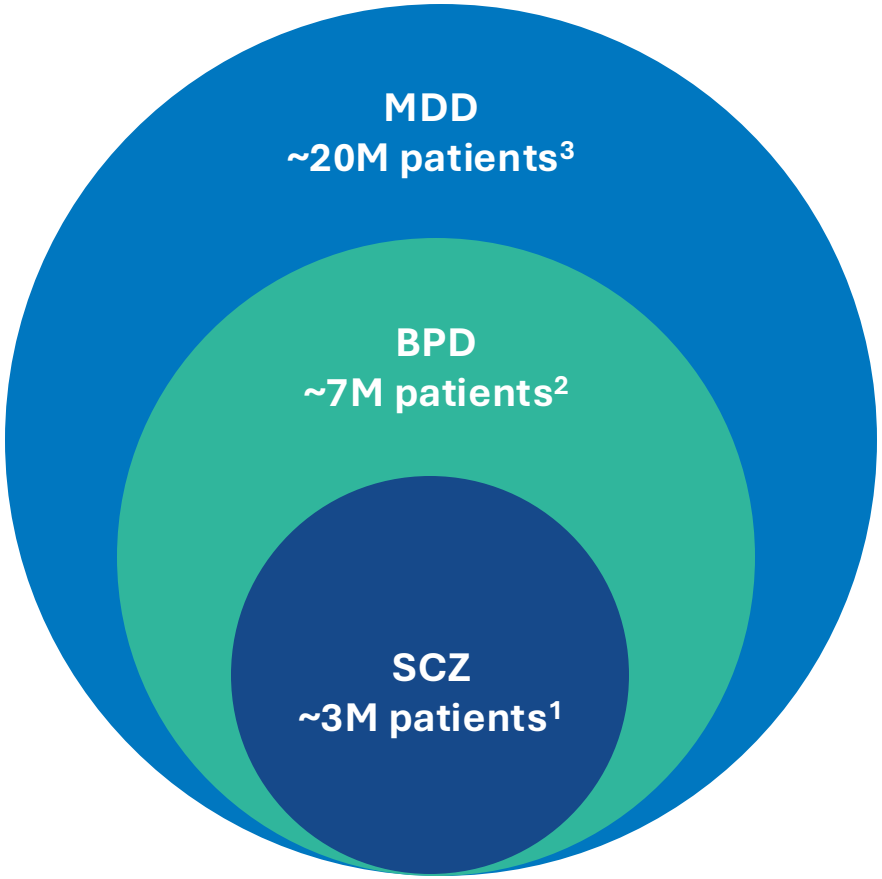
[1] Neuropsychopharmacology, 2024, 50, 372-377; [2]ACS Omega, 2019, 4, 14151-14154; LB Pharma proprietary data

LB-102's Mechanism, Phase 2 Data, and the Legacy of Amisulpride All Support Development in Psychosis and Mood Disorders

LB-102 and amisulpride have a distinct CNS receptor binding profile among APs

- Mechanism supports activity in both psychosis and mood disorders
- LB-102 Ph 2 data demonstrated clinical activity in SCZ, negative symptoms, cognition and potential for improved tolerability
- Amisulpride clinical experience supports potential for broad range of efficacy

Large Target Market for APs with Attractive Attributes and Well-Established Development Paths



Development of APs typically starts in SCZ, with higher doses and premium pricing, expands to BPD to establish a foothold in depression, and then broadens to MDD

Numerous blockbuster products:

2024 US sales
- Vraylar >$3.3B
- Abilify >$1.7B
- Rexulti >$1.5B

High value acquisitions:

Intra-Cellular acquired for $14.6B

[1] https://www.hopkinsmedicine.org/health/wellness-and-prevention/mental-health-disorder-statistics#:~:text=Approximately%201%25%20of%20Americans%20are,late%20teens%20or%20early%2020s. ;
[2] https://www.nimh.nih.gov/health/statistics/bipolar-disorder; [3] https://www.nimh.nih.gov/health/statistics/major-depression#:~:text=disorders%2C%20or%20medication.-,Prevalence%20of%20Major%20Depressive%20Episode%20Among%20Adults,more)%20races%20(13.9%25); 2024 sales data from EvaluatePharma

Schizophrenia

Schizophrenia is a Prevalent and Debilitating Disease with No Cure

Epidemiology / Burden

~3M people in U.S.[1]

Estimated 5% of schizophrenia patients die by suicide[2]

29-year decrease in average overall life expectancy[3]

Current Treatments

D2 antagonists

D2 partial agonists

M1/M4 Muscarinic Receptor Agonist

Unmet Needs (Efficacy)

~60% of patients with negative symptoms[4]

~ 80% with cognitive impairment[5]

Both are poorly addressed by treatments

Unmet Needs (Safety)

Sedation, EPS, GI effects, and weight gain are common

45% of switches between agents are due to intolerability or safety issues[6]

Compliance

Lack of compliance leads to relapse

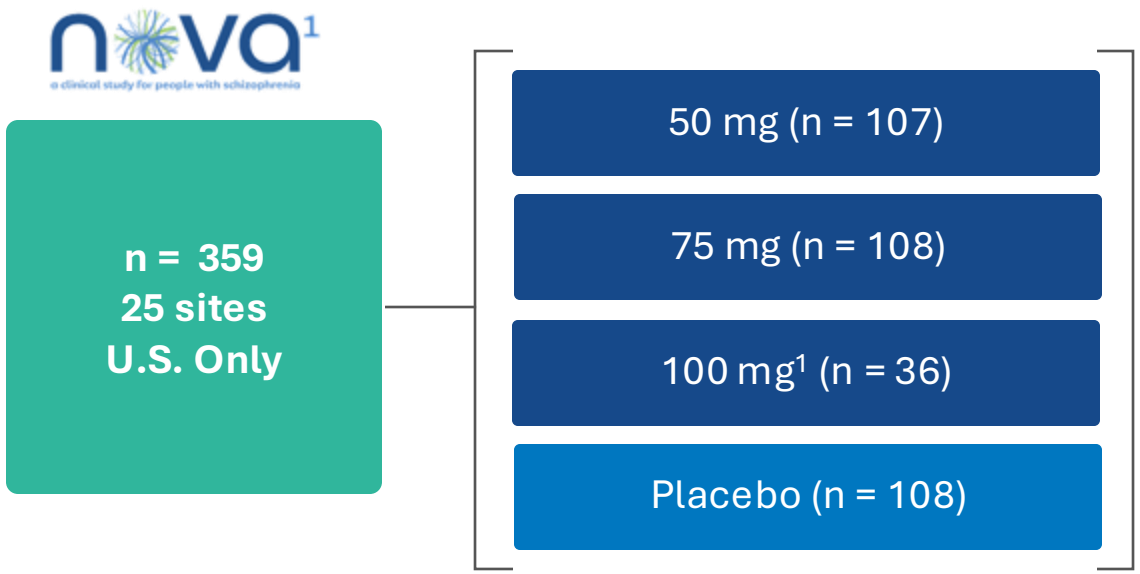
BID dosing, food effects contribute to compliance issues

74% of patients discontinue in 18 months[7]

LB-102 has potential to address many of the key limitations of current treatments for schizophrenia

[1] Schizophrenia Statistics in the U.S. 2025 | Facts about Schizophrenia – The Global Statistics [2] N Engl J Med. 2005;353:1209–1223; Harvey et al., Schizophr Res Cogn. 2022;29:100249 ; [3] J of Mental Health and Hum Behavior 2023; 28(2): 111-115 [4] N Engl J Med. 2005;353:1209–1223; [5] Harvey et al., Schizophr Res Cogn. 2022;29:100249 [6] J of Mental Health and Hum Behavior 2023; 28(2): 111-115 [7] *BMC Psychiatry* **18**, 135 (2018). https://doi.org/10.1186/s12888-018-1724-9

Successful Phase 2 Acute SCZ Trial Has Potential to Be One of Two Pivotal Trials Required for Approval



Primary Endpoint:
PANSS Δ from baseline at day 28

Secondary Endpoints:
CGI-S, PANSS positive and negative subscales, Marder factor

Exploratory Endpoint: Cognition

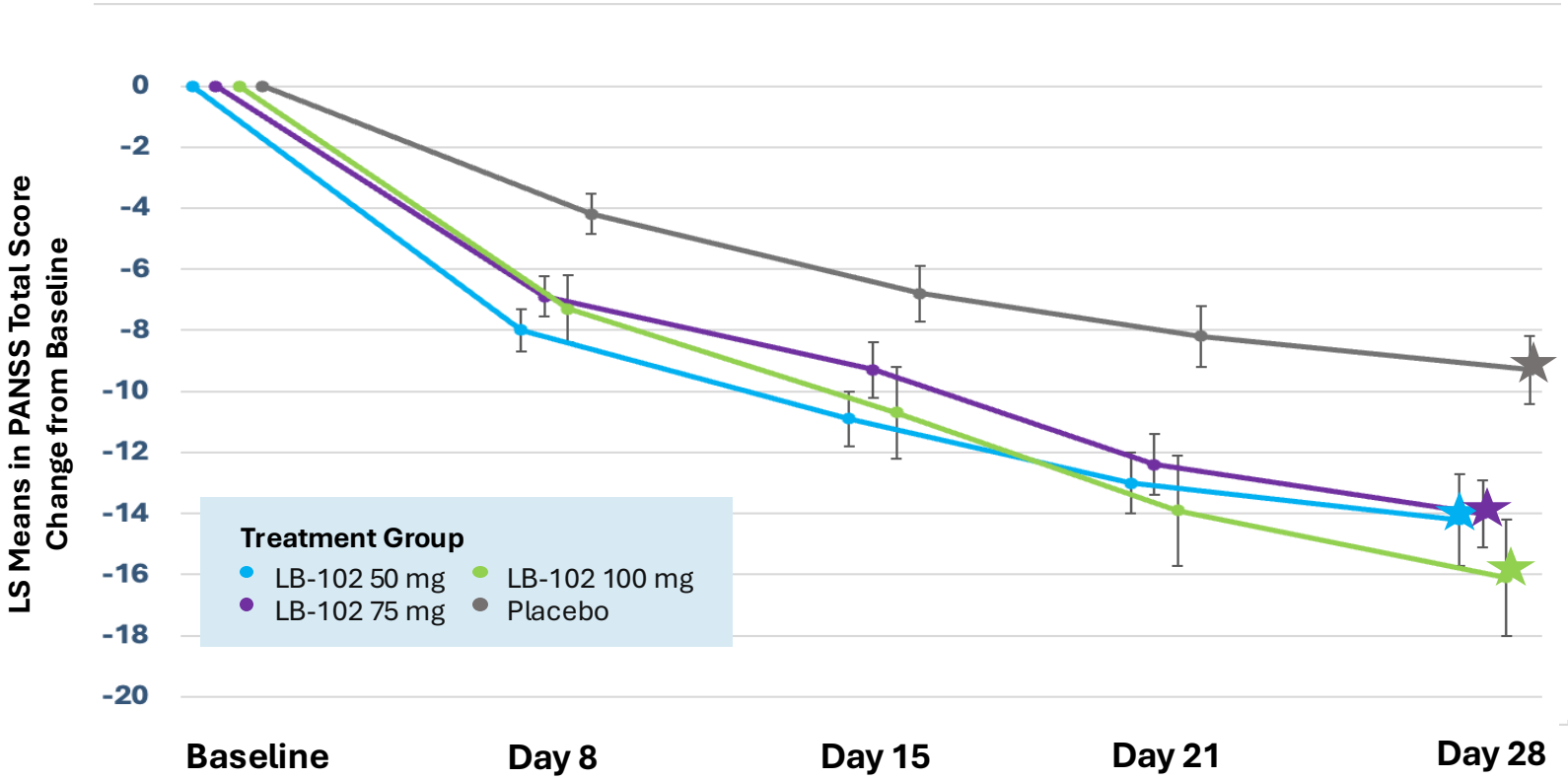
Designed trial to be potentially pivotal with large sample size, robust statistical analyses, conservative imputation of missing data

FDA noted, in writing, that our Phase 2 trial appeared to have many of the characteristics of an adequate and well-controlled trial – one successful Phase 3 required for approval

[1] Exploratory dose;

Statistically Superior Clinical Activity to Placebo at All Three Doses

Clinically meaningful PANSS reduction in 4-week SCZ trial (baseline PANSS of 94)



PANSS Δ from baseline (Δ vs. Placebo)

50 mg
-14.3 (-5.0 vs. Pbo)
(p=0.0009)

75 mg
-14.0 (-4.7 vs. Pbo)
(p=0.0022)

100 mg
-16.1 (-6.8 vs. Pbo)
(p=0.0017)

Pbo
-9.3

Numerous measures implemented to control placebo rate including screening to exclude professional patients, use of central raters, scale minimization, and close oversight of sites and CROs

LS Mean = least squared mean; SEM = standard error of the mean, PANSSΔ is defined as change in PANSS from baseline to day 28

Compelling Treatment Effect at Doses Planned for Phase 3

	Dose	Effect Size vs Pbo (completers)	Effect Size vs Pbo (MMRM)
LB-102 (Phase 2)	50 mg	0.61	0.50
	100 mg	0.83	0.64

- Results for LB-102 are near the top of effect size (ES) reported for approved first-line APs[1]
- ES for 100 mg dose are in the range of those previously reported for amisulpride
- ES for 100 mg dose across both methods are greater than those reported for Cobenfy (0.56)[2]

Results demonstrate statistical robustness of Phase 2 trial and provide confidence heading into Phase 3

[1]The Lancet. 2019;394(10209):939–949; [2]European Neuropsychopharmacology. 2025;92;62-73; Effect size is calculated by taking the difference in average PANSS change between two groups (an active treatment arm and placebo) and dividing it by the pooled standard deviation. Completer analysis includes observed data from patients who received the protocol specified four weeks of treatment; MMRM refers to Mixed Model for Repeated Measures. MMRM analysis includes observed and imputed data from all patients with at least one post baseline PANSS assessment

Robust, Dose-Dependent Effect on Cognition, a Key Unmet Need

Global composite effect in cognition[1]

	Dose	Effect Size vs Pbo	p	n
LB-102 (Phase 2)	50 mg	0.26	0.0476	84
	75 mg	0.41	0.0027	74
	100 mg	0.66	0.0018	20

Global composite effect on cognition represents composite of five tests covering psychomotor function, memory, attention, working memory and executive function

- Significant, dose-dependent improvement in cognition consistent with LB-102 mechanism
- Magnitude of benefit represents a significant potential advantage over existing therapies
- High rate of satisfactory completion of tests demonstrates reliability of data
- Broad patient population without enriching for severe cognitive impairment at baseline
- Unmet need spans SCZ, BPD and MDD[2]

[1] Cognition was evaluated as an exploratory endpoint in our Phase 2 clinical trial utilizing the CogState Computerized Schizophrenia Battery of Tests, a well validated measure of cognitive ability in subjects with schizophrenia. Effect size versus placebo was calculated in a post hoc analysis after excluding certain outliers that did not meet the test performance pass quality control metric;[2]Horan et al., 2025 Schizophrenia Bulletin, 51 (2) , 262–273

Favorable Adverse Event (AE) Profile in Phase 2

Adverse Events Reported in ≥5% of Patients Number of subjects (% of treatment group)	50 mg (N=107)	75 mg (N=108)	100 mg (N=36)	Placebo (N=108)
Insomnia	27 (25.2%)	23 (21.3%)	14 (38.9%)	24 (22.2%)
Headache	12 (11.2%)	9 (8.3%)	2 (5.6%)	10 (9.3%)
Anxiety	10 (9.3%)	9 (8.3%)	4 (11.1%)	9 (8.3%)
Agitation	11 (10.3%)	6 (5.6%)	4 (11.1%)	10 (9.3%)
Weight increase	13 (12.1%)	8 (7.4%)	3 (8.3%)	4 (3.7%)
Hyperprolactinemia	11 (10.2%)	8 (7.5%)	6 (16.6%)	0
Blood creatine phosphokinase increased	4 (3.7%)	1 (0.9%)	2 (5.6%)	3 (2.8%)
Alanine aminotransferase increased	3 (2.8%)	1 (0.9%)	2 (5.6%)	1 (0.9%)
Somnolence	1 (0.9%)	4 (3.7%)	2 (5.6%)	0
Constipation	4 (3.7%)	1 (0.9%)	2 (5.6%)	0

- Most AEs were mild or moderate in severity and similar to placebo
- AEs leading to discontinuation were reported at the following rates: 50 mg (1.9%), 75 mg (2.8%), 100 mg (8.3%), Pbo (1.9%)
- Serious Adverse Events (SAE) occurred at the following rates: 50 mg (less than 1%), 75 mg (less than 1%), 100 mg (2.8%), Pbo (1.9%)
- Comorbid conditions at entry influenced reporting of TEAEs which were defined as any AE that began on or after the first dose, or any pre-existing condition that reappeared during treatment or follow up. As a result, AEs such as insomnia appear elevated
- Weight gain reflects any increase without a threshold. We observed ~1.6 kg placebo adjusted weight gain without concerning metabolic signals

Low Rate of EPS is a Potential Differentiator that Resonates with Clinicians

Total EPS Observed in LB-102 Phase 2 Trial
Number of subjects (% of treatment group)

Preferred Term	50 mg (N=107)	75 mg (N=108)	100 mg (N=36)	Placebo (N=108)
Dystonia	0	3 (2.8%)	1 (2.8%)	1 (0.9%)
Akathisia	1 (0.9%)	2 (1.9%)	0	1 (0.9%)
Extrapyramidal disorder	0	1 (0.9%)	1 (2.8%)	2 (1.9%)
Total EPS	**1 (1.0%)**	**6 (5.6%)**	**2 (5.6%)**	**4 (3.7%)**

- EPS is generally correlated with dopamine receptor occupancy (RO) rate
- EPS rates (including akathisia) observed with other D2 antagonists and partial agonists can reach more than 30%
- EPS rates lower than amisulpride
- Low EPS despite high RO for LB-102

Additional data expected in 2026 to elucidate the reasons for low rate of EPS

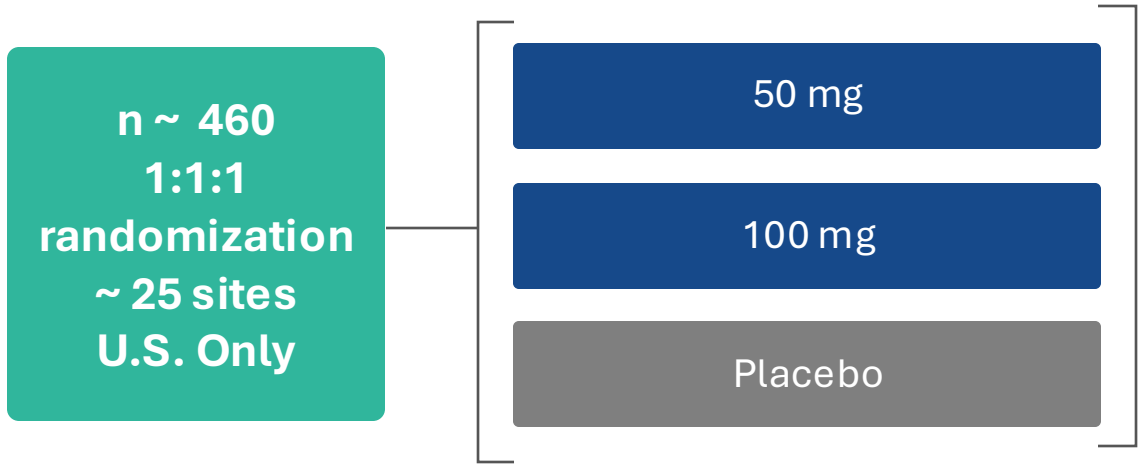
EPS related adverse events were generally mild to moderate in severity. One event of dystonia (75 mg LB-102) was considered an SAE.

Potentially Class Leading Safety Profile Also Includes Negligible Sedation, Few Prolactin-related AEs, and Low QTc Prolongation

Prolactin-related AEs	Low rate (~1-5.6%); AEs were mild to moderate and did not result in discontinuation
Sedation	Single case of sedation among 251 patients exposed to LB-102 in Phase 2 trial
QTc Prolongation	Minimal QT prolongation (4.3-5.4 ms); no patients met pre-specified stopping criteria

Adverse events of interest were generally mild to moderate in severity. QTcF = Fridericia-corrected QT interval. The QT interval is the time between the start of the Q wave and the end of the T wave on an ECG, representing the time it takes for ventricular depolarization and repolarization; Stopping criteria defined per FDA guidance of an increase of more than 60 ms or an absolute QT interval of more than 500 ms

Planned Phase 3 SCZ Clinical Trial Design Aligned with FDA



Primary Endpoint:
PANSS at day 42 (6 weeks)

Secondary Endpoints:
CGI-S, PANSS positive and negative subscales, Marder factor, cognition·

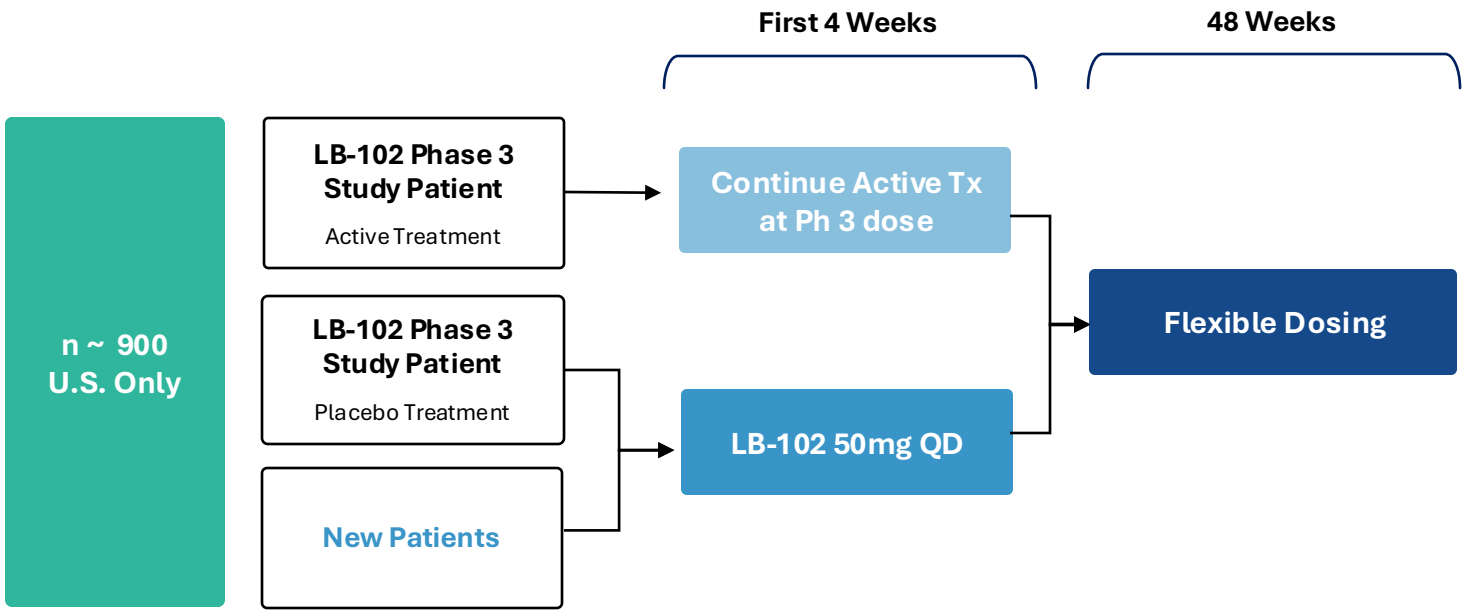
Similar in scope to Phase 2 – primary changes are 6-wk treatment duration and 3 versus 4 arms

Expect significant site overlap between Ph 2 and Ph 3
Same CRO, efficacy scales, approximate number of sites, Pbo control measures, and principal investigator

Low execution risk given high degree of similarity to Phase 2
Topline data read out expected in 2H 2027
Doses selected to inform both acute treatment and maintenance in commercial setting

Innovative Open Label Extension (OLE) Provides Requisite Safety Dataset for Approval and Supports Differentiation at Launch

LB-102 52-week OLE Trial Design



Designed to enroll both patients who participated in the Phase 3 trial as well as new patients to accrue safety dataset

Primary Endpoint:
Safety

Secondary Endpoints:
PANSS

Subset Analyses:
cognition, prominent negative symptoms

Supports accrual of safety database sufficient for approval
Subset analyses intended to inform future development and augment LB-102 profile at launch

LB-102 has Potential to be a Branded AP of Choice in SCZ

Compelling Evidence of Clinical Activity

Clinically meaningful PANSS reduction across all three tested dose levels

Strong treatment effect (e.g., ES) at both 50 and 100 mg

6-week Phase 3 trial has potential to further improve PANSS reduction

Potentially Class Leading Safety Profile + Simple Dosing

Low EPS, QTc prolongation, negligible sedation

Simple once daily dosing

No food effect or DDIs

Few anticholinergic effects

Differentiated Effects in Cognition and Negative Symptoms

Robust, dose dependent treatment effect on cognition

Significant effect on negative symptoms at 50 mg dose

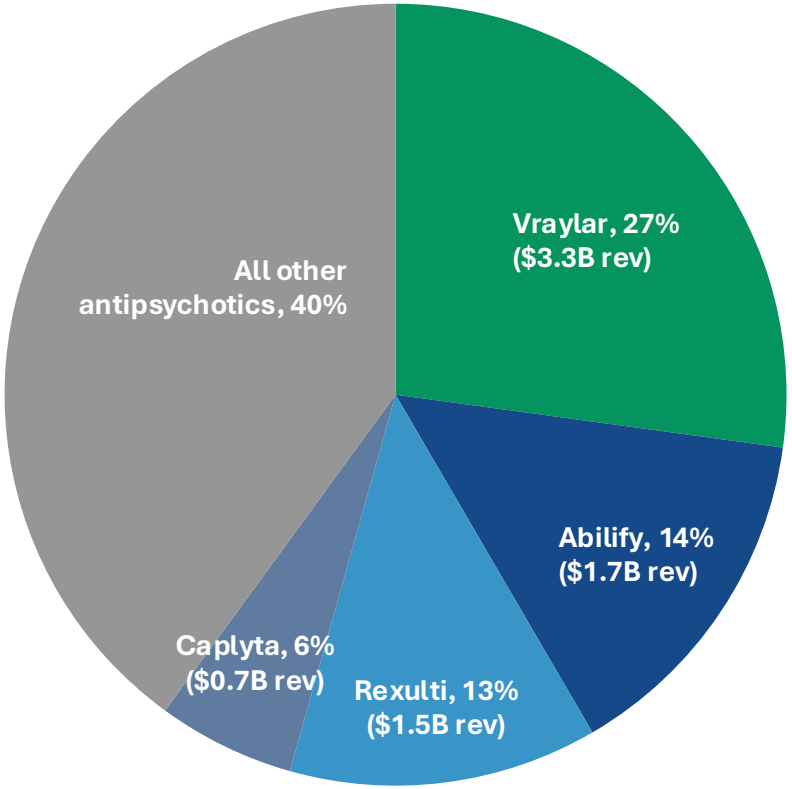
Additional supporting data from OLE available at launch

Potential to be first-in-class benzamide in the U.S. for the treatment of SCZ

Bipolar Depression

Achieving Blockbuster Status Typically Requires Expansion Beyond SCZ

2024 Branded AP Sales in U.S.: ~$12B
Four Branded APs Account for ~60% of Sales



- **Vraylar Approvals:** SCZ, Bipolar Mania, ***BPD, MDD***
- **Abilify Approvals:** SCZ, Bipolar Mania, ***MDD***, Autism, Tourette's
- **Rexulti Approvals:** SCZ, ***MDD***, Alzheimer's agitation
- **Caplyta Approvals:** SCZ, ***BPD, MDD***

2024 sales data from EvaluatePharma; Approved indications from individual product labels in the U.S.;

Bipolar Depression is an Attractive Initial Opportunity in Mood Disorders with Unmet Needs that Align Well with the Emerging Profile of LB-102

Epidemiology / Burden

~ 7M patients in U.S. and 40M worldwide[1]

Patients alternate between manic and depressive states

Higher baseline levels of function than SCZ patients

Current Treatments

Mood stabilizers and APs are the mainstay

APs can control depression, mania

SSRI / SNRI can trigger manic events; rarely used

Unmet Needs (Efficacy)

Fewer approved therapeutics

~ 60% have cognitive impairment[2], anhedonia[3]

Both are poorly addressed by treatments

Unmet Needs (Safety)

Especially sensitive to AEs that can impact function

High rates of sedation, EPS, GI side effects despite lower doses

Compliance

Lack of compliance leads to relapse

BID dosing, food effects contribute to compliance issues

~ 60% of patients switch therapy due to safety or efficacy[4]

Potential for LB-102 to have competitive efficacy, improved safety, with low rates of EPS and sedation, and a positive and differentiating impact on cognition / anhedonia

[1] LB-102 https://www.who.int/news-room/fact-sheets/detail/bipolar-disorder; Qualitative Interviews conducted Sept/Oct 2024. Source: Physician Interviews (N=30), Physician Follow-Up Interviews (N=5), Physician Survey (N=168 Schizophrenia, N=100 Bipolar Depression), ClearView Analysis; LB Analysis; LB Pharma bipolar depression Advisory Board [2]Tsapekos et al. BMC Psychiatry (2023) 23:842 https://doi.org/10.1186/s12888-023-05327-1 [3] Whitton et al. Curr Topics Behav Neurosci (2022) 58: 111–128 https://doi.org/10.1007/7854_2022_323 [4] LB Pharma proprietary data

Compelling Strategic Rationale for Development in BPD Alongside SCZ

Global Revenue Opportunity	Amisulpride has no label anywhere in the world for BPD
High Probability of Success	Strong scientific and clinical rationale based on LB-102 Phase 2 data Legacy of clinical experience with amisulpride in depression
Streamlined Path to Approval	Safety dataset from SCZ approval reduces cost and timeline to BPD approval
Attractive Commercial Dynamics	Initial approval in SCZ enables premium pricing in mood disorders Low competitive intensity leads to high commercial share of voice
Supports Indication Expansion & LCM	Success in BPD supports expansion to MDD and augments opportunity for LAI

; At that time of potential LB-102 approval in BPD, Caplyta may be the sole branded agent since Vraylar is expected to go off patent in 2029

Derisked Development of LB-102 in BPD Based on Three Pillars

LB-102 Mechanism and Phase 2 Data

D2, D3, 5HT7 targeting provides antidepressant activity, mania control

Phase 2 SCZ data demonstrates ability to control mania (a milder form of psychosis)

Favorable safety profile and positive effects on cognition

Validating Precedent Clinical Data in MDD and BPD

As good or better than Paxil, Zoloft and significantly better than Pbo[1]

Compelling antidepressant activity in BPD with non-racemic ami[2]

MDD and BPD have similar imbalance in neurotransmitters[3]

Elegant Phase 2 Trial Design

Fixed-flexible dose design

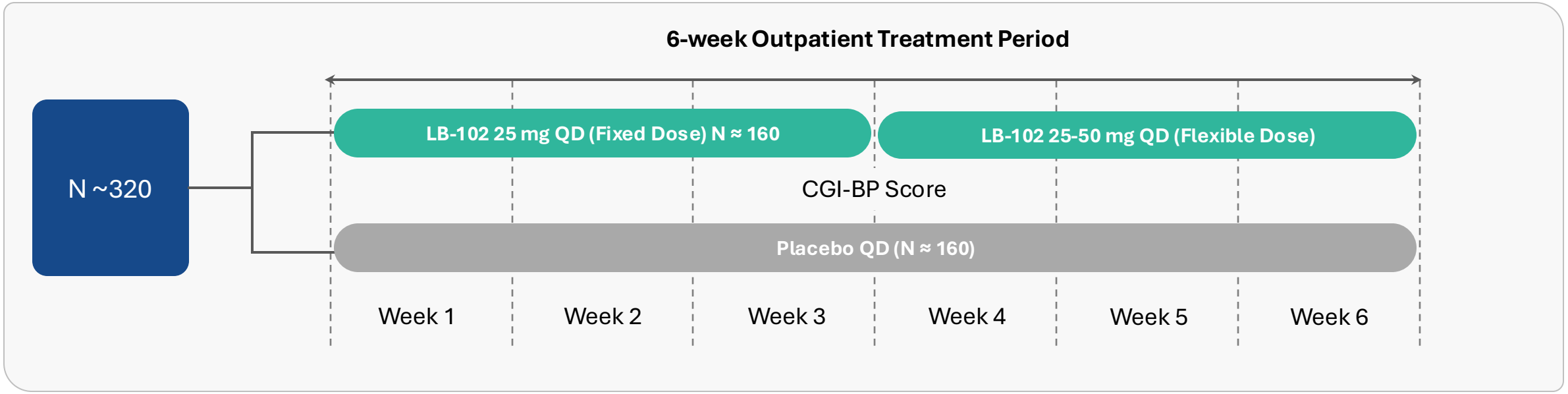
Allows investigation of two doses of LB-102 in a two-arm trial

Maximizes probability of response while minimizing placebo rate

We believe there is a high POS as we begin Phase 2 development in BPD

[1]Cassano GB, et al. Int Clin Psychopharmacol. 2002;17(1):27-32.; Amore M, et al. Int Clin Psychopharmacol. 2001;16(6):317-324; Zoloft and Paxil approved for MDD; [2]Journal of Affective Disorders. 2022;296(10209):549-558; https://clinicaltrials.gov/study/NCT05169710?intr=SEP-4199&rank=2&tab=results; [3] Clin Psychol Rev. 2005 May;25(3):307-39

Phase 2 Trial Design Maximizes Potential for Clinical Response



- ~ 320 patients, 30 sites, U.S. only, two arms
- 25 mg fixed dose (first 3 weeks), flexible dose of 25 or 50 mg (Weeks 4-6), randomized 1:1
- Primary endpoint: MADRS-10 at Week 6, all LB-102 treated patients vs Placebo
- Secondary endpoints: MADRS-6, CGI-BP, Cognition, Anhedonia, Safety, and Tolerability
- Designed to be registrational
- Two-arm and flexible dose design mitigate placebo effect[1]

Topline data read out expected in 1Q 2028

[1]Kahn et al, Neuropsychopharmacology 2003 Mar;28(3):552-7; CGI-BP-I refers to the Clinical Global Impression-Bipolar Illness (CGI-BP) scale

Future Directions

Numerous High Value Expansion Opportunities

Major depression (MDD)

Amisulpride approved ex-U.S. for dysthymia[1]

Amisulpride demonstrated to be as effective as approved agents for MDD[2]

Predominantly negative symptoms of SCZ:

Amisulpride outperformed placebo in three independent studies for negative symptoms[3]

Approved for SCZ with negative symptoms in the UK and Australia[1]

Alzheimer's Disease (AD) psychosis and agitation

40% of ~7M Americans with AD experience psychosis or agitation[4,5]

Amisulpride demonstrated clinical benefit in AD psychosis[6] and was well-tolerated in elderly patients[7]

Strong Clinical Rationale for Expansion into Additional Psychosis and Mood Disorders

[1] Solian label; [2]Cassano GB, et al. Int Clin Psychopharmacol. 2002;17(1):27-32.; Amore M, et al. Int Clin Psychopharmacol. 2001;16(6):317-324; [3] Boyer et al, British Journal of Psychiatry (1995), 166, 68-72; 2Danion et al, Am J Psychiatry 1999; 156:610-616; 3Loo et al Br J Psychiatry. 1997 Jan:170:18-22; Ther Adv Psychopharmacol. 2018;8:303–318; [4] Alzheimer's & Dementia, 2023;19;1598-1695; [5]Chem. Pharm. Bull, 2024;72;610-617; [6]J. Clin. Psych., 2017;78;e844-e851; 7Lancet Psychiatry, 2018;5:553-563

Compelling Lifecycle Opportunity with LAI Formulation

LAI's reduce risk of relapse

Improved compliance

Consistent drug exposure

Reduced hospitalization and improved functional outcomes earlier in the disease[1]

LB-102 LAI

Potential first-in-class benzamide LAI globally

Supports global market expansion in SCZ and BPD

Formulation development planned in 2026

[1]Schizophrenia, 2023, 9; [2] Third party company financials and analyst reports

LB Pharma is Building a Fully Integrated CNS-focused Company

De-Risked Approach with Late-stage Trials Planned in Schizophrenia (SCZ) and Bipolar depression (BPD)

Positive Phase 2 Data Highlights Potential for Differentiated Profile in $12B Branded AP Market[1]

Streamlined Path to Approval in SCZ with a Single Phase 3 Trial Based on Positive FDA Feedback

Compelling Expansion Opportunities with Strong Scientific and Clinical Rationale, Life Cycle Management

Robust IP Portfolio with Issued Composition of Matter (COM) Protection Through 2041[2]

Strong Balance Sheet from Recent IPO that Supports Multiple Clinical Read-outs

[1] AP = antipsychotic; 2024 sales data from EvaluatePharma; [2] Includes estimated Hatch-Waxman extension, composition of matter IP expires 2037; LB-102 patent portfolio includes: 7 U.S. issued, 11 foreign issued, 7 U.S. pending, and 19 foreign pending patents

LB Pharmaceuticals Inc

Thank you!

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