LB Pharmaceuticals Inc

Developing Novel Therapies for Neuropsychiatric Disorders

January 2025

pharmaceuticals

Potential to Transform the Treatment of Neuropsychiatric Disorders

Strong safety and efficacy in schizophrenia	Potential first benzamide antipsychotic (AP) in the U.S.; successful Phase 2 results; Phase 3 initiation in 2025 and data expected in 2027
Opportunity to pursue other indications	Potentially providing another 12M addressable patients in other neuropsychiatric disorders
Opportunity to pursue LAI	$6B market opportunity as first benzamide long-acting injectable (LAI)
Proven leadership	Track record of successful biotech execution, value creation, and psychiatry expertise

World-class Leadership Backed by Premier KOLs and Investors

Heather Turner
Chief Executive Officer/Director

Former CEO of Carmot Therapeutics, multiple CEO/ COO and biotech leadership roles

Anna Eramo, MD, Psychiatrist
Chief Medical Officer

Previously led U.S. clinical and medical affairs at Lundbeck, responsibilities included psychiatric portfolio products

Roger Sawhney, MD
Chief Financial Officer

Former CFO of Omega Therapeutics and Garuda Therapeutics, ex-KKR, ex-Novartis Chief Strategy Officer

Andrew Vaino, PhD
Chief Science Officer

Former SVP of R&D at Retrophin, previously biotech analyst at Roth Capital

Board of Directors

Scott Garland	Board Chair
Rajul Jain, MD	Vida Ventures
Rebecca Luse	Deep Track Capital
Ran Nussbaum	Pontifax
Robert Ruffolo, PhD	Former Head of R&D, Wyeth
Chen Yu, MD	TCGX
Zachary Prensky	Founder

Scientific Advisors

John Kane, MD	Zucker School of Medicine
Christoph Correll, MD	Zucker School of Medicine, Charite – University Medicine, Berlin, Germany
Stefan Leucht, MD	Technische Universität München

Leading life science investor syndicate

DEEP TRACK CAPITAL · VIDA ventures · TCGX · PONTIFAX

Significant Unmet Need Persists in Schizophrenia

Limited Efficacy for Too Many Patients

- ~50% of patients fail to respond to existing therapies[1]
- Current treatments primarily target positive symptoms

The Burden of Negative Symptoms

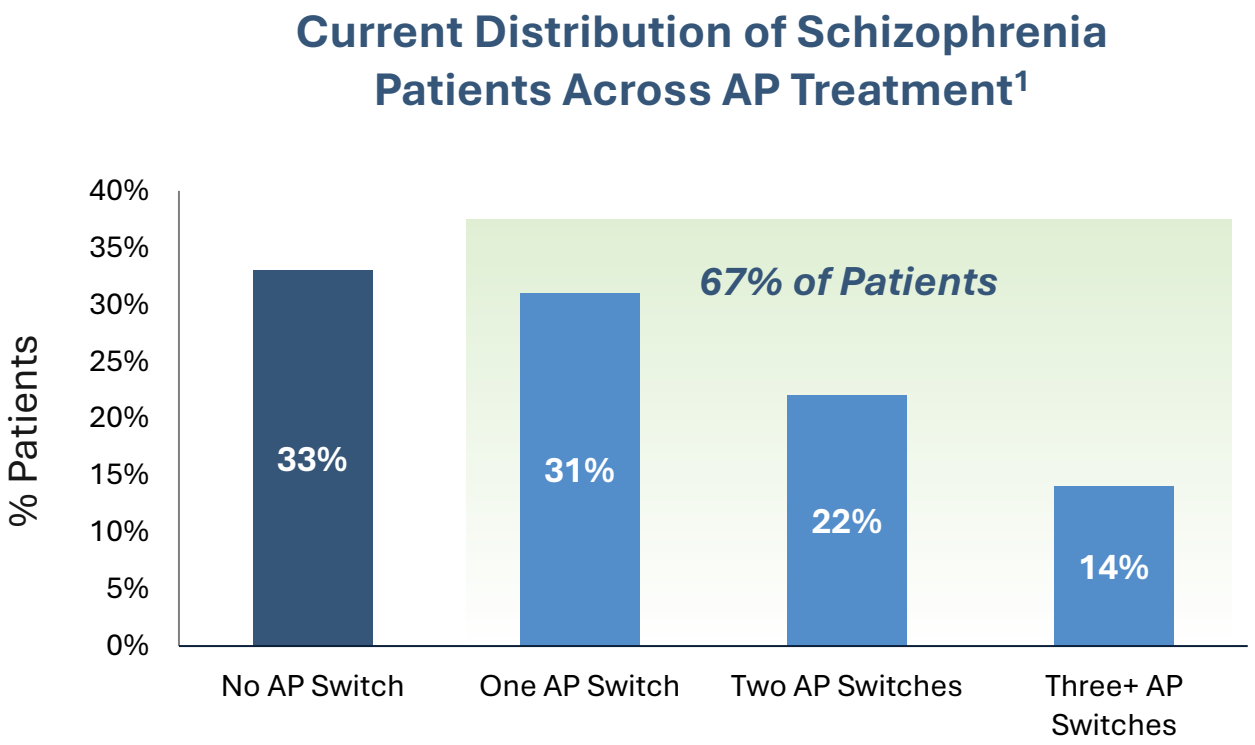
- Up to 60% of patients[2]
- Significant impact on QoL, but poorly addressed by current and emerging treatments

Side Effects and Compliance Issues

- Sedation, extrapyramidal symptoms (EPS), GI (nausea, vomiting, etc.), weight gain, and metabolic dysfunction
- 67% of patients discontinue or switch therapies[3]

[1] Schizophrenia Res. 2009;115:97–103; [2] N Engl J Med. 2005;353:1209–1223; [3] LBPharma Market Research (Physician Survey, n=160)

Widespread AP Switching Highlights Therapeutic Shortfalls



67% of treated schizophrenia patients switch APs due to limited efficacy or tolerability[1]

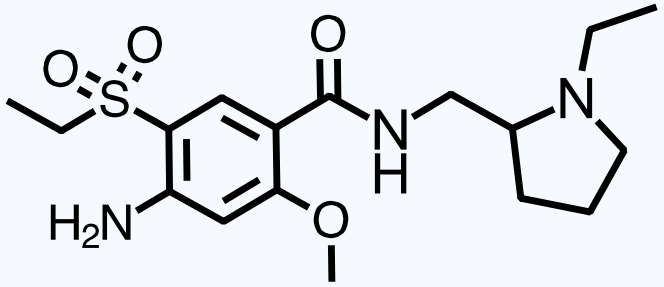
45% of switches are due to intolerability/ safety issues[2]

[1] LBPharma Market Research (Physician Survey, n=160); [2] J of Mental Health and Hum Behavior 2023; 28(2): 111-115

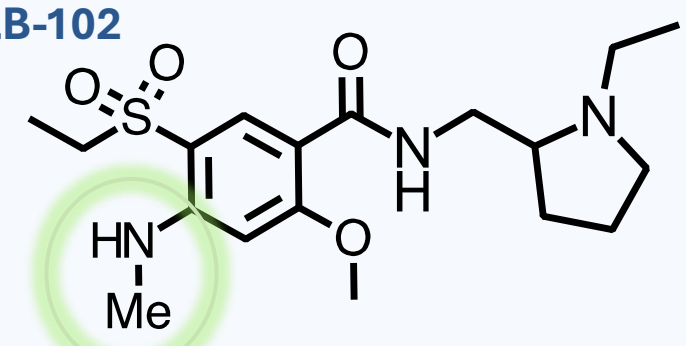
New Chemical Class for Treatment of Schizophrenia in U.S.

Amisulpride profile enhanced by adding a methyl group

Amisulpride



LB-102



Intellectual Property

- Composition of matter until at least 2040[1]
- Patents: 7 U.S. issued, 11 foreign issued; 2 U.S. pending, 24 foreign pending

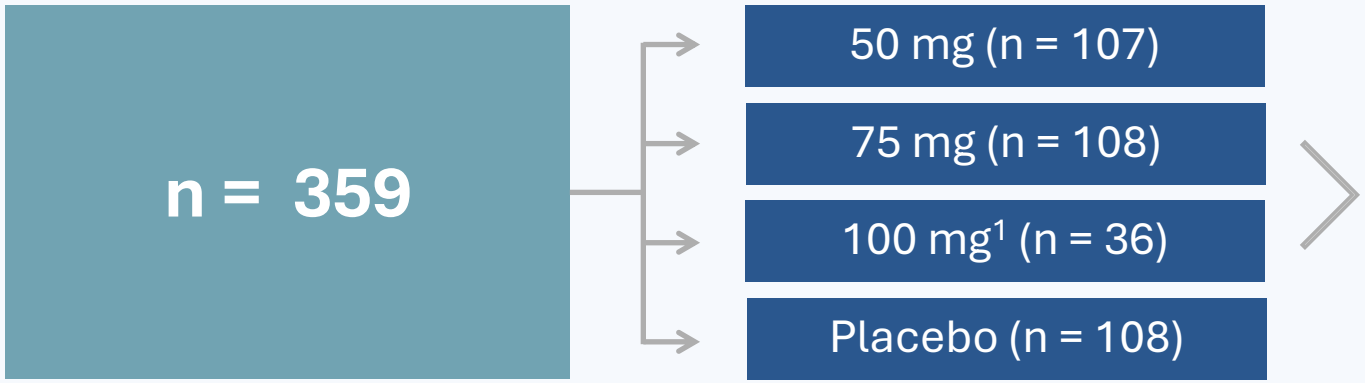
[1] *Includes estimated Hatch-Waxman extension*

Phase 2 NOVA[1] Clinical Trial Design

4-week, in-patient, double-blinded, placebo-controlled, oral once daily dose in acute schizophrenia patients

- 359 patients at 19 U.S. clinical trial sites
- Initiated in November 2023
- 50 mg, 75 mg, 100 mg[1] and placebo (randomized: 3:3:1:3)
- Designed to be potentially considered registrational

nova[1]
a clinical study for people with schizophrenia



Primary endpoint: Change from baseline in Positive and Negative Syndrome Scale (PANSS) at 28 days

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

Safety and tolerability

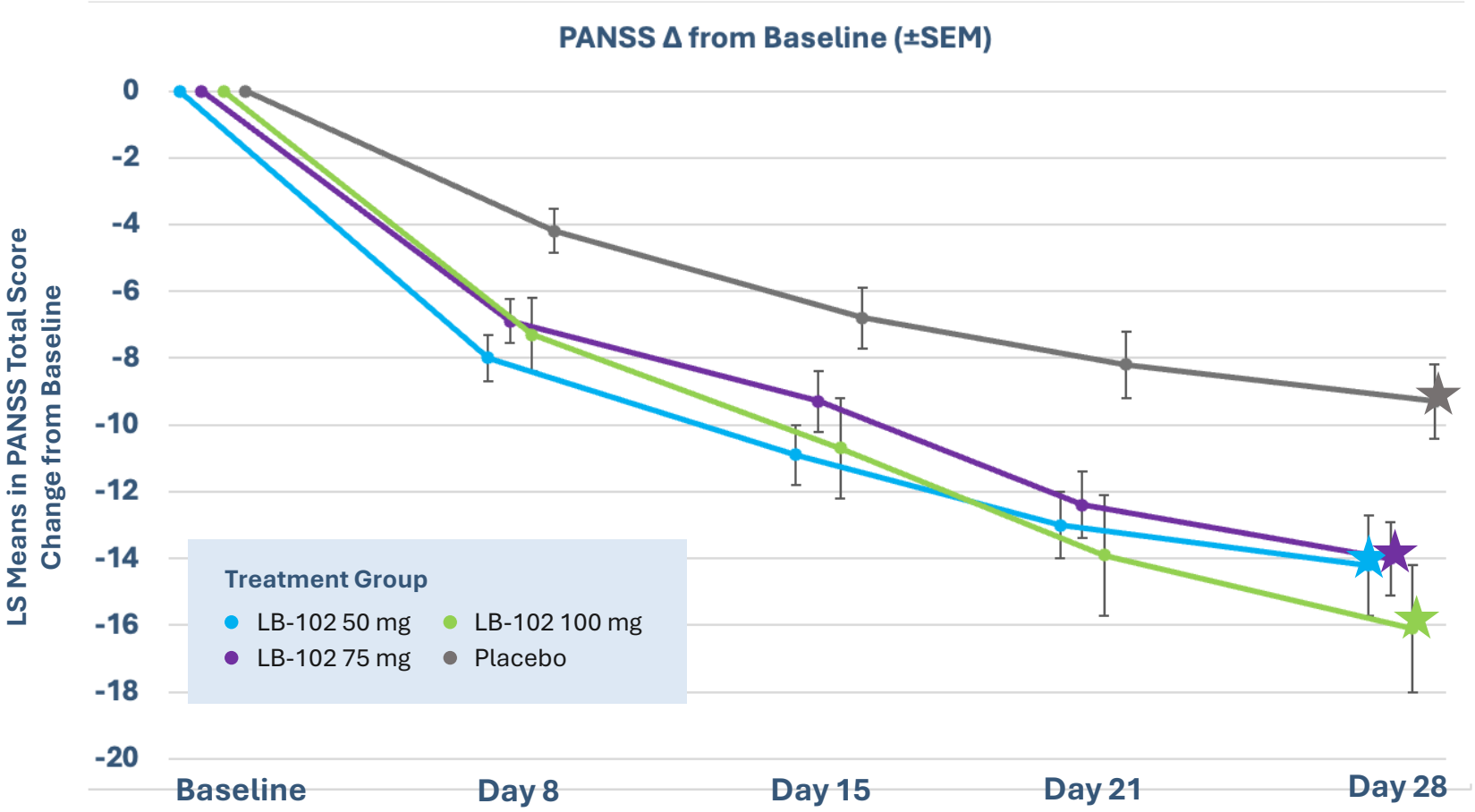
[1] Exploratory dose

Baseline Demographics Consistent with Other Schizophrenia Trials

	50 mg	75 mg	100 mg	Placebo	Overall
n	107	108	36	108	359
Age at IC (SD)	39 (9.6)	39.2 (9.2)	39.1 (9.2)	39.1 (9.2)	39.1 (9.3)
Male n (%)	87 (81)	90 (83)	28 (78)	85 (79)	290 (81)
Female n (%)	20 (19)	18 (17)	8 (22)	23 (21)	69 (19)
Latino n (%)	12 (11)	8 (7)	6 (17)	17 (16)	43 (12)
White n (%)	17 (16)	18 (17)	9 (25)	24 (22)	68 (19)
Black n (%)	87 (81)	83 (77)	25 (69)	80 (74)	275 (77)
Asian n (%)	0	2 (2)	0	1 (1)	3 (1)
Native American n (%)	0	2 (2)	0	0	2 (2)
Weight at BL kg (SD)	84 (20)	88 (18)	86 (18)	86 (17)	86 (18)
PANSS at BL (SD)	94 (7)	94 (8)	94 (9)	94 (8)	-

IC: Informed Consent; SD: Std Deviation; PANSS: Positive and Negative Symptoms Syndrome Scale; BL: Baseline

Statistically Superior Efficacy to Placebo at All Three Doses



Effect Size vs. Placebo

Dose	Effect Size
50 mg vs. PBO	0.61
75 mg vs. PBO	0.41
100 mg vs. PBO	0.83

PANSS 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

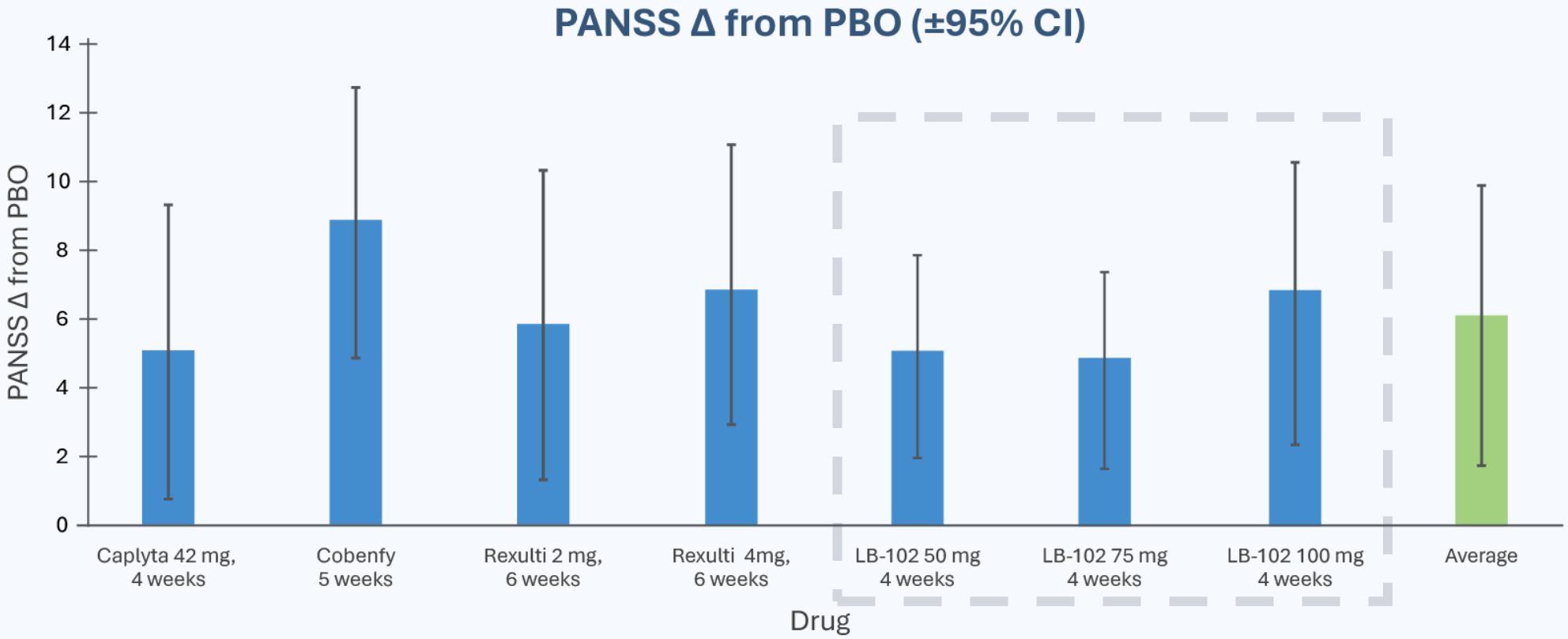
100 mg Dose Effect Size Greater than Approved SCZ Drugs

Drug	Effect size (Overall change in symptoms)
Clozaril/Clozapine[1]	0.89
Solian/Amisulpride[1]	0.73
Risperdal/Risperidone[1]	0.55
Invega/Paliperidone[1]	0.49
Abilify/Aripiprazole[1]	0.41
Latuda/Lurasidone[1]	0.36
Vraylar/Cariprazine[1]	0.34
Rexulti/Brexpiprazole[1]	0.26
Cobenfy/KarXT[2,3]	0.56

LB-102 Dose	Effect size (Overall change in symptoms)[3]
LB-102 (100 mg)	**0.83**
LB-102 (50 mg)	**0.61**
LB-102 (75 mg)	**0.41**

[1]The Lancet. 2019;394(10209):939–949; [2]European Neuropsychopharmacology. 2025;92;62-73
[3]LB-102 and Cobenfy effect size estimate are similar to those reported above, which used a network meta-analysis of effect size to derive a more robust estimate for treatment.

PANSS Δ In Line with Recently Approved SCZ Drugs



Adverse Events Reported in ≥5% of Patients

Number of subjects (% of treatment group)

Preferred Term	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 increased	13 (12.1%)	8 (7.4%)	3 (8.3%)	4 (3.7%)
Hyperprolactinemia[1]	11 (10.3%)	8 (7.4%)	6 (16.7%)	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

[1]Combined Adverse Event Terms “Hyperprolactinemia” and “Blood Prolactin Increased”

Adverse Events of Interest

EPS

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%)**

Sedation

Number of subjects (% of treatment group)

Preferred Term	50 mg (N=107)	75 mg (N=108)	100 mg (N=36)	Placebo (N=108)
Sedation	0	1 (0.9%)	0	0

Related to prolactin increase

Number of subjects (% of treatment group)

Preferred Term	50 mg (N=107)	75 mg (N=108)	100 mg (N=36)	Placebo (N=108)
Galactorrhea	2 (1.9%)	1 (0.9%)	0	0
Breast enlargement	0	0	1 (2.8%)	0
Erectile dysfunction	0	0	1 (2.8%)	0
Total related to Prolactin	**2 (1.9%)**	**1 (0.9%)**	**2 (5.6%)**	**0**

QTcF Prolongation

QTcF Δ from Baseline at Day 28 (ms)

	50 mg (N=107)	75 mg (N=108)	100 mg (N=36)	Placebo (N=108)
Baseline	393.4	394.7	390.0	393.4
Day 28	**4.9**	**4.3**	**5.4**	**1.7**

Stopping criteria not met at any dose

AE Related Trial Discontinuations and SAEs

Discontinuations Due to AEs by Dose

Dose	%	Reported AE
50 mg	1.9%	Suicidal ideation*, Exacerbation of psychosis+
75 mg	2.8%	COVID-19o, Dystonia*, Increased amylase and lipaseo
100 mg	8.3%	Toothacheo, Increased ALT*, Exacerbation of psychosiso
Placebo	1.9%	Exacerbation of psychosis (n=2) *+

Serious Adverse Events

Dose	%	Reported AE
50 mg	<1%	Suicidal ideation*
75 mg	<1%	Acute dystonic drug reaction*
100 mg	2.8%	Exacerbation of psychosiso
Placebo	1.9%	Deatho, Exacerbation of psychosiso

Relationship to Treatment

* = Possibly Related + = Related o = Not related

Potential to Compete in Schizophrenia and Other Markets

- **Statistically superior efficacy to placebo at all doses**
  - Marked effect sizes were observed at all doses (50 mg = 0.61; 75 mg = 0.41; 100 mg = 0.83)
  - Clinically meaningful PANSS reduction at all three doses
  - Efficacy comparable to other approved antipsychotics
- **Generally safe and well tolerated**
  - AEs observed, if replicated, have potential to be class leading relative to other D2/D3 antagonists
  - Low incidence of overall EPS and AEs related to hyperprolactinemia
  - Minimal QTcF interval prolongation; stopping criteria not met
- **50 mg success opens opportunities for market expansion**
  - LAI formulation
  - Additional neuropsychiatric disorder indications

nova1
a clinical study for people with schizophrenia

Potential to Address ~12M Patients in Additional Indications

Predominantly negative symptoms of SCZ:

~1 million U.S. patients

- Amisulpride outperformed placebo for negative symptoms[3]
- Approved for SCZ with negative symptoms in the UK and Australia[1]

Bipolar depression (BPD):

~7 million U.S. patients

- Receptors targeted by LB-102 hypothesized to impact BPD
- Approved ex-US for dysthymia[1] and used off-label for BPD[2]

Alzheimer's Disease (AD) psychosis and agitation:

~4 million U.S. patients

- 40% of ~7M Americans with AD experience psychosis or agitation[4,5]
- Amisulpride demonstrated clinical benefit in AD psychosis[6] and showed safety in elderly patients[7]

[1] Solian label; [2] Proprietary Company Research; [3] 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; [7]Lancet Psychiatry, 2018;5:553-563

Potential to be Formulated as an LAI

LAI's are key to reduce the risk of relapse

Consistent drug exposure

↓

Improved compliance

↓

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

LB-102 LAI

- Opportunity for novel IP
- Global market expansion
- ~$6 billion market opportunity[2]
- IND submission in 2027

[1] *Schizophrenia*, 2023, 9
[2] *Company financials and analyst reports*

Multiple Expected Inflection Points Within Next 24 Months

		Preclinical	Phase 1	Phase 2	Phase 3	Anticipated milestones
LB-102 (Oral)	Acute Schizophrenia	Phase 3				• Initiation Q4 2025
	Expansion Indication(s)	Phase 2				• Initiation Q1 2026
	Elderly Population (>65 years)	Phase 1 safety trial				• Initiation Q1 2025
LB-102 (LAI)	LAI Formulation	Formulation development				• DC Selection 2026; IND Submission 2027

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Opportunity to pursue LAI	Enables $6B market opportunity as first benzamide long-acting injectable (LAI)
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Thank you!
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