pharmaceuticals

SACHS BIOCAPITAL USA FORUM

MARCH 21, 2018

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LB PHARMACEUTICALS INVESTMENT HIGHLIGHTS

- Schizophrenia (SCZ) is a debilitating disease affecting 3 million Americans
  - Despite > a dozen approved drugs 60% of patients not adequately treated
  - LB-102 is a novel variant of Amisulpride, one of the most effective and safe schizophrenia drugs approved worldwide **(never approved in the US!)**
  - Biological and chemical properties of LB-102 (structure, PK, CNS receptor binding, animal behavior, rat toxicity) are consistent with Amisulpride
  - Patent filed, should provide IP until 2037+
- 60 million Rx/year in US for SCZ
  - Estimated 2% market share (Amisulpride share in EU) affords $1+ billion annual sales in US
- Rivopharm SA, world's biggest supplier of Amisulpride, has invested $850k to date in LB Pharmaceuticals and provides manufacturing support
- Complete IND package for LB-102 in 12 months; initiate Phase 1 clinical trial mid-2019

MANAGEMENT

Zachary Prensky, CEO & Co-Founder

- Experienced biotechnology and pharmaceutical investor
- Managed family office from 2000-2015
- Has 18+ year history of strategic consulting in the biotech industry (Datascope, Caliper, Emisphere, Aldeyra, and others)

Vince Grattan, Co-Founder

- Board member and senior consultant to LB Pharmaceuticals.
- A PA registered pharmacist currently employed by MHM Services, responsible for all facets of drug utilization management collaborating with a team of 300+ clinicians
- Has 20 years of experience in psychopharmacology

Dr. Andrew Vaino, CSO

- Former VP of R&D at Retrophin, Inc.
- Invented and brought drug to treat PKAN from idea to dosing in humans in under 2 years

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

Advisory Board

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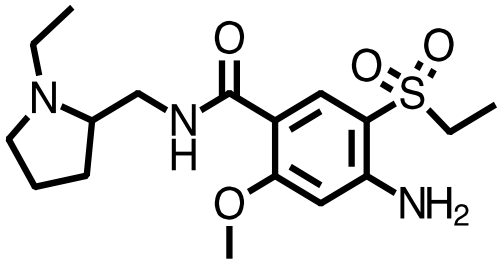
LB-102: AN IMPROVED AMISULPRIDE

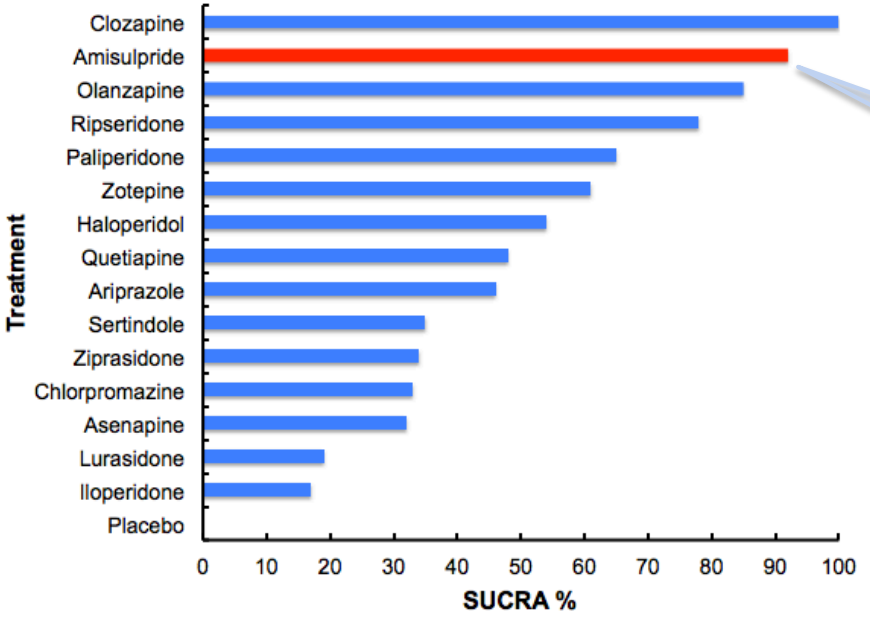
- Amisulpride is a schizophrenia drug marketed in Europe since 1986



- Selective D_2 (K_i = 2.8 nM)/D_3 (K_i = 3.2 nM) and $5HT_7$ (K_i = 31 nM) antagonist
- 30 years of clinical use demonstrates an excellent safety/efficacy profile
- LB-102 has a comparable selectivity profile to Amisulpride with no discernible differences at key receptors (D_2, D_3, $5HT_2$, $5HT_7$, etc.)
- LB-102 rat 14-day toxicology profile is consistent with Amisulpride
- In head-to-head studies, LB-102 was comparable to or superior to Amisulpride in three rodent schizophrenia models

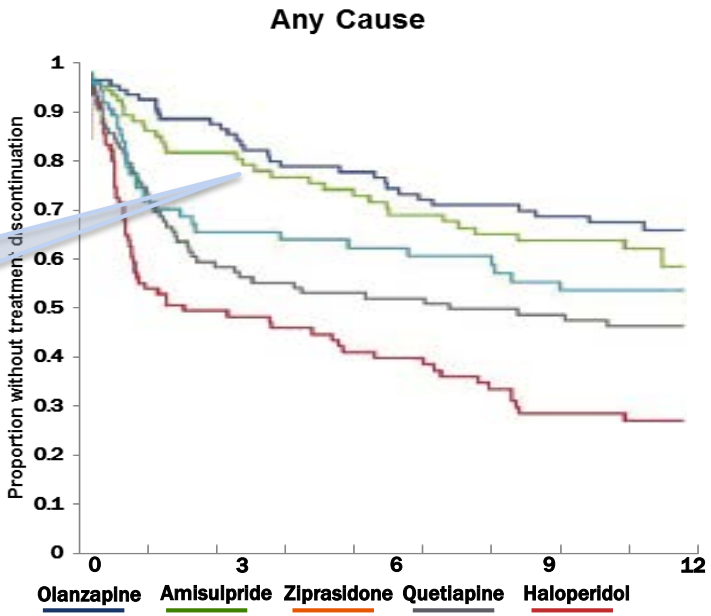
AMISULPRIDE ONE OF MOST EFFECTIVE SCZ DRUGS

COMPARATIVE META-ANALYSIS (n = 43,000) OF 15 ANTIPSYCHOTIC DRUGS *



Amisulpride is one of the most effective antipsychotics in the world.

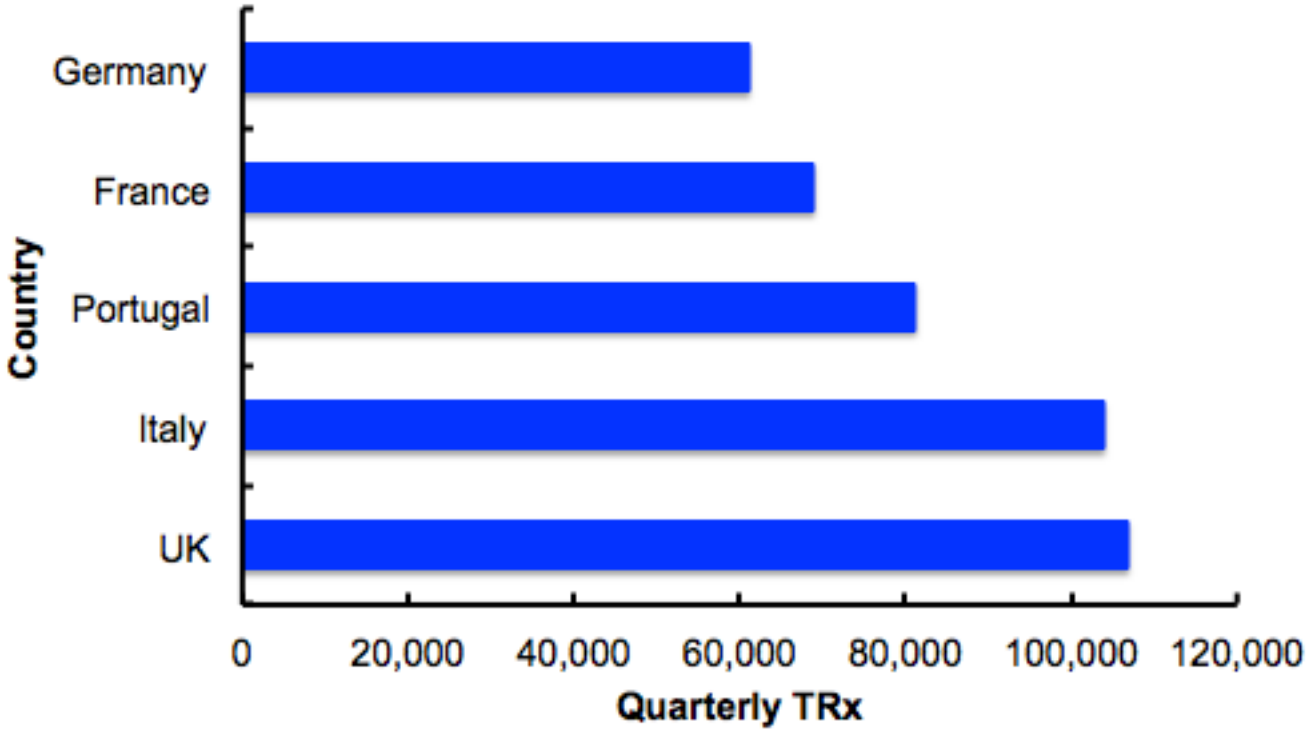
Amisulpride has one of the lowest discontinuation rates of any antipsychotic



* Leucht *et al.*, *Lancet* , **2013**, *382*, 951-962.

SUCRA = Surface Under the Cumulative Ranking, a measure that compares efficacy of drug to an intervention that is always the best

> 2 MILLION ANNUAL AMISULPRIDE EU RX



- Amisulpride maintains an estimated 2% market share of antipsychotics for all indications in EU
  - ~ 2 million scripts per year; steady usage over past 5 years
  - Closely related Sulpiride also has a 2% market share

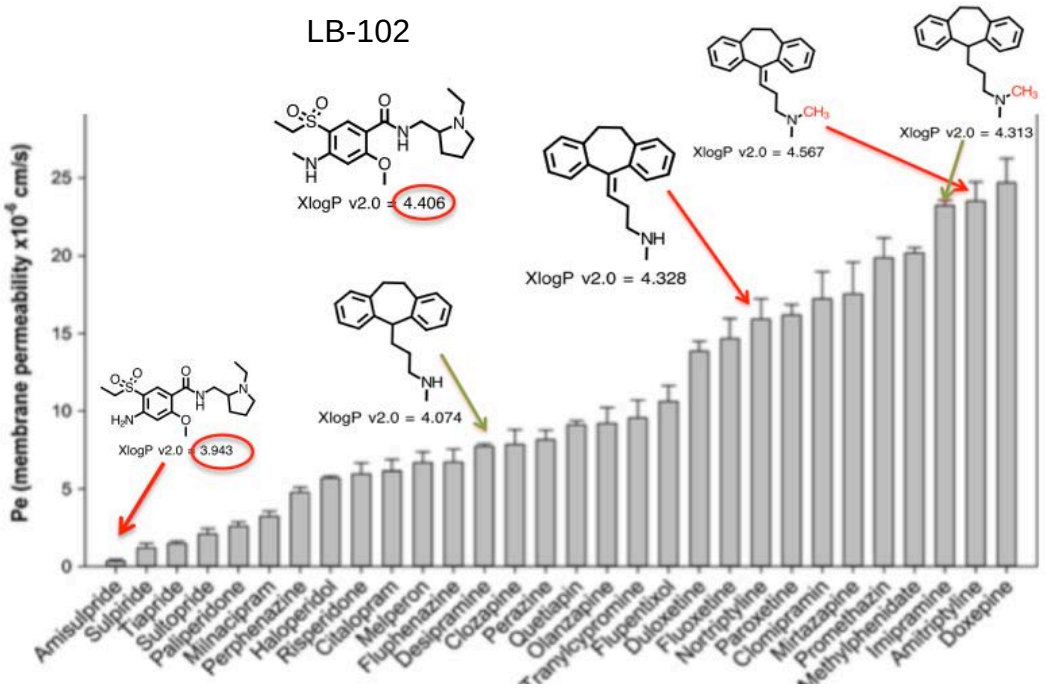
AMISULPRIDE DIFFERENTIATING FACTORS

- As effective as gold standard second generation antipsychotics Risperidone and Olanzapine at treating symptoms of SCZ*
- Fewer occurrences of weight gain and sedation than Olanzapine, Quetiapine, and Risperidone (first-line standard of care), and less EPS than Risperidone*
- Lower risk of self-harm after SCZ diagnosis than Olanzapine or Risperidone**
- In ESCAPE study*** 78% of SCZ patients switching to Amisulpride from Risperidone and 56% switching from Olanzapine had > 50% improvement in PANSS at 8 weeks
- In recent meta-analysis**** Amisulpride was the only antipsychotic (of 34, including Olanzapine and Risperidone) that outperformed placebo in treatment of negative symptoms
- **Despite a strong record of efficacy and safety and clear differentiation from other anti-psychotics, Amisulpride is unavailable to schizophrenia patients in the United States**

*Leucht *et al. Lancet,* **2013**, *382*, 951-962
Ma *et al. Acta. Psychiatr. Scand.,* **2018, *1-10*
***Liang and Yu, *Neuropsychiatric Disease and Treatment*, **2017**, *13*, 1163-1173
****Krause *et al.*, *European Archives of Psychiatry and Clinical Neuroscience*, **2018,**
https://doi.org/10.1007/s00406-018-0869-3

BBB ISSUES DECREASE AMISULPRIDE EFFICACY

- Of 30 psychiatric medications tested Amisulpride was least able to passively diffuse across Blood Brain Barrier*

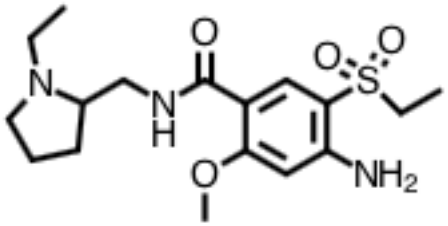


- Addition of a single methyl group (i.e. Amisulpride to LB-102) to an amine can have a profound impact on BBB permeability by increasing cLogP by 10%

**The AAPS Journal*, 2014, *16*, 1247-1258

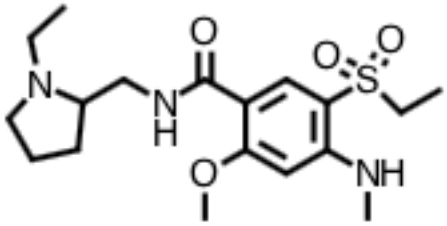
LB-102: A NOVEL BENZAMIDE

Amisulpride



MW = 369.5
cLogP = 3.94

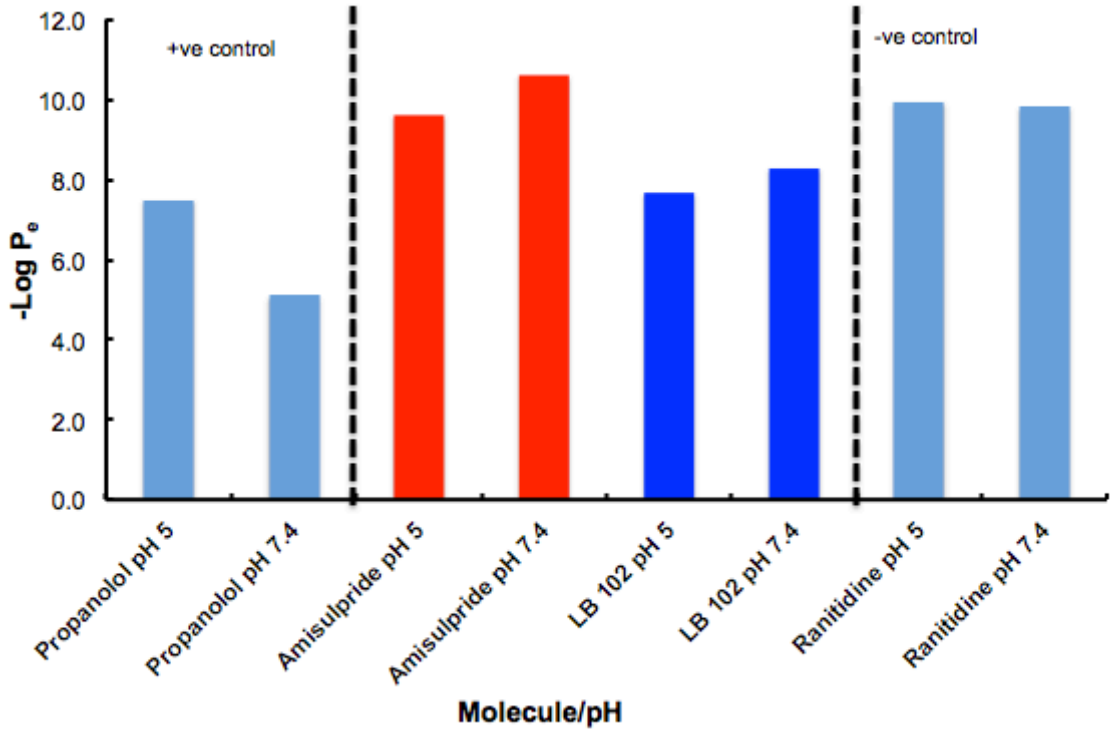
LB-102



MW = 383.5
cLogP = 4.41

- LB-102 designed to improve delivery to the brain while minimally affecting receptor binding
- PCT and US patent application (filed November 2017) covers composition of matter
- *In vitro* data suggests that LB-102 has greater membrane permeability than Amisulpride
- LB-102 shows equivalent, and in some cases better, efficacy in animal models of schizophrenia compared to Amisulpride

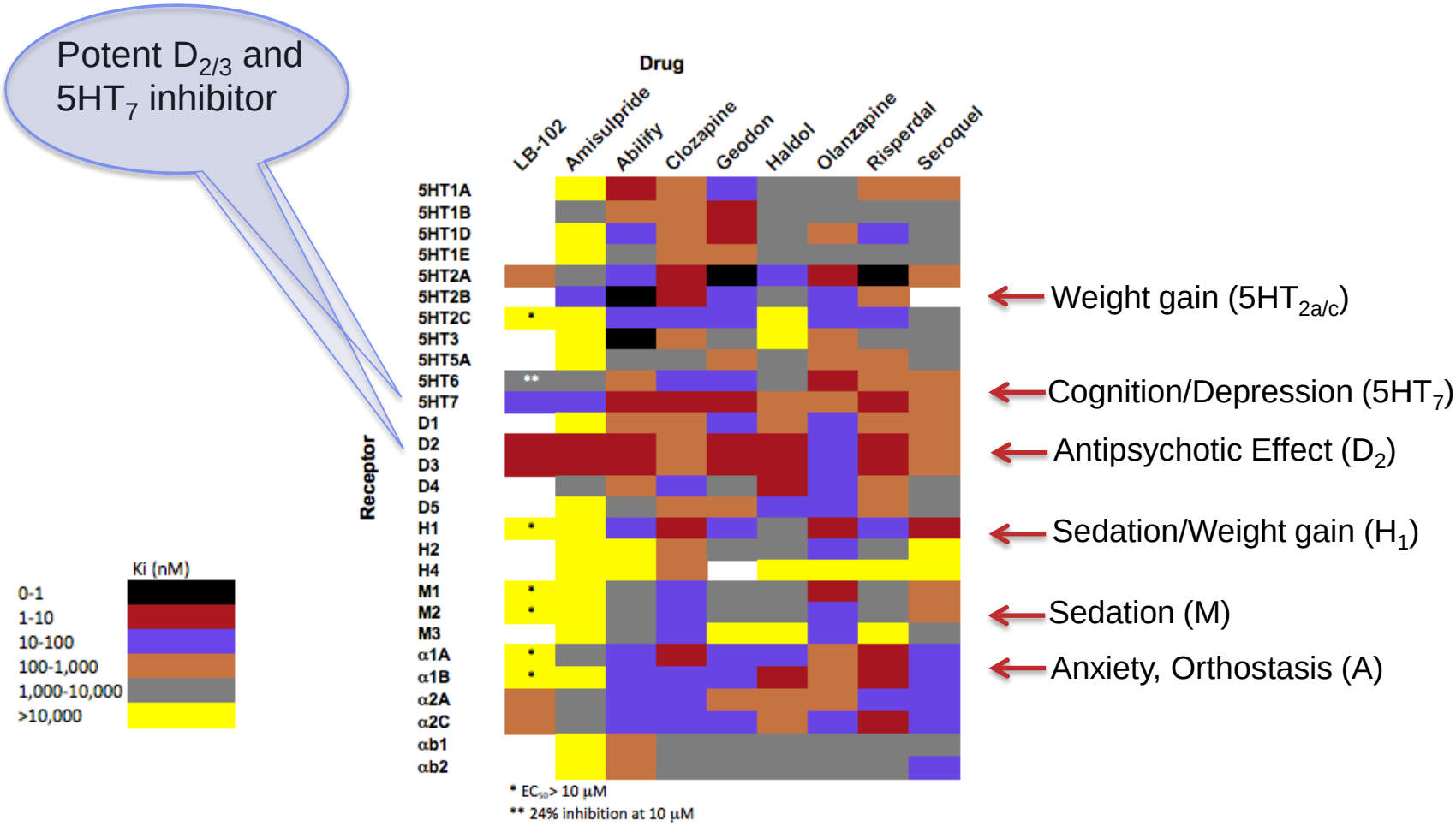
LB-102 *IN VITRO* BRAIN PERMEABILITY DATA



- In PAMPA assay LB-102 was ~200X more permeable than Amisulpride

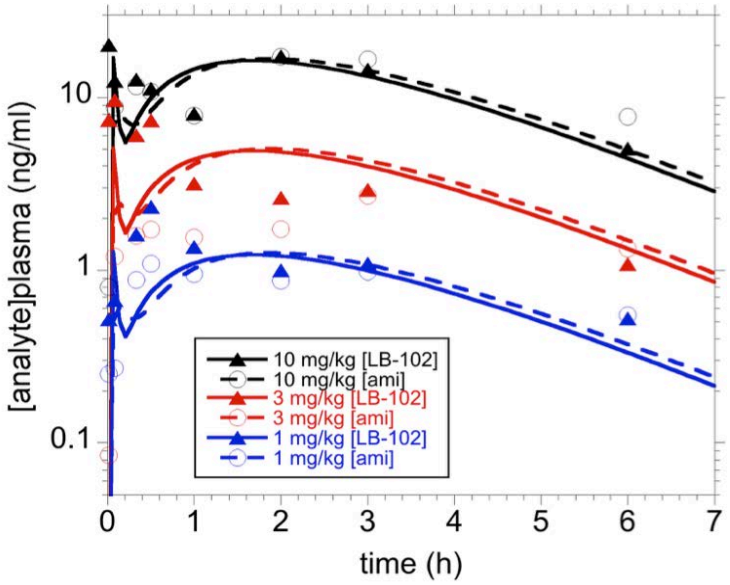
LB-102 AND AMISULPRIDE RECEPTOR SPECIFICITY

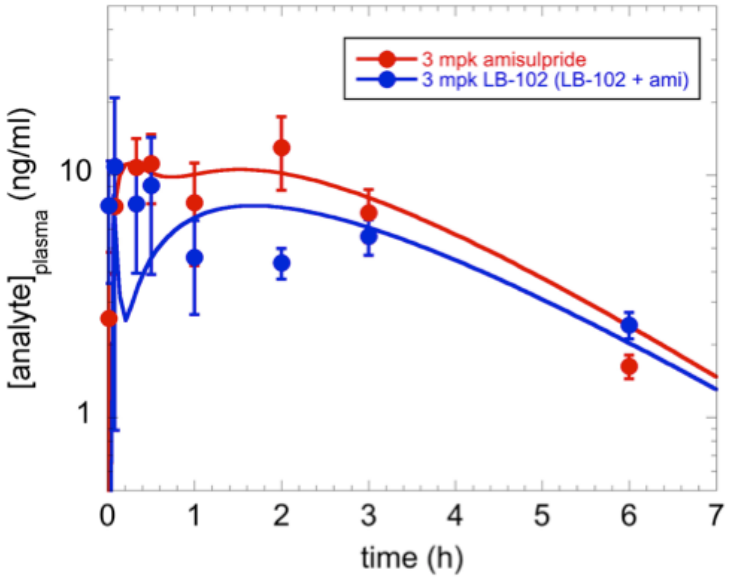
LB-102 cleanly binds $D_{2/3}$ and $5HT_7$ receptors (like Amisulpride)---decreases off-target effects



Ki data from: *The Neuroscientist*, 2000, *6*, 252-26245rf

LB-102 PHARMACOKINETICS EQUIVALENT TO AMISULPRIDE

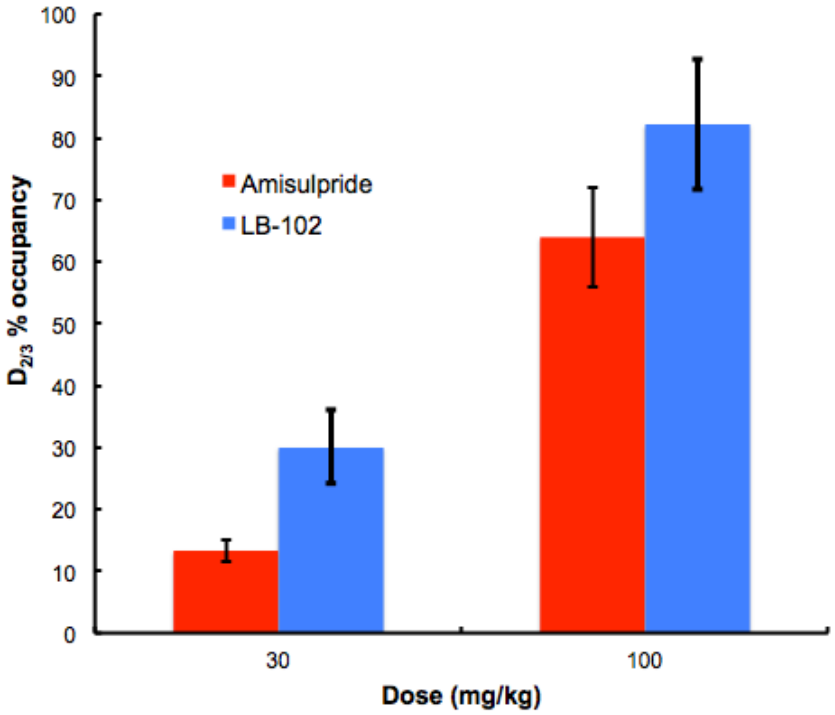




- Total benzamide (LB-102 + Amisulpride) plasma exposure of orally dosed LB-102 is similar to Amisulpride and is linearly dose dependent
- Note, LB-102 is ~50% demethylated to Amisulpride in rats
  - Demethylation likely CYP-driven and expected to be lower in humans

LB-102 RAT BRAIN $D_{2/3}$ RECEPTOR OCCUPANCY (RO)

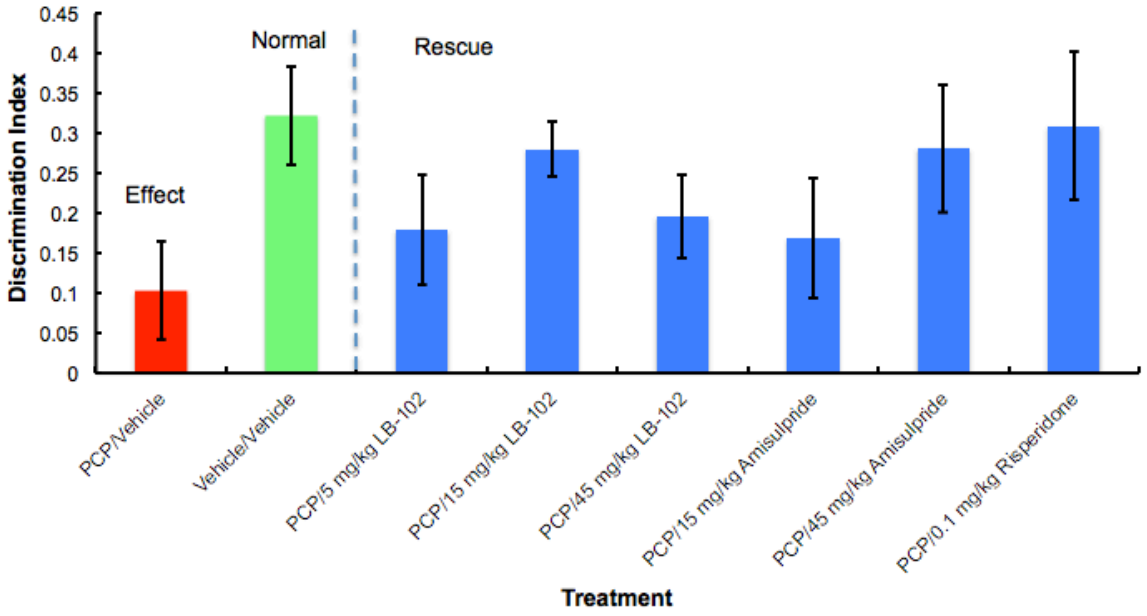
Dopamine % Receptor Occupancy in rat brains (n = 3/group) 12h after PO doses of LB-102 or Amisulpride



- Initial *in vivo* data suggests greater dopamine RO in rat brains for LB-102
- In humans, dopamine RO is highly correlated to improvements in PANSS

NOVEL OBJECT RECOGNITION (NOR) STUDY

- NOR is a widely published and validated animal model of cognitive impairment in SCZ



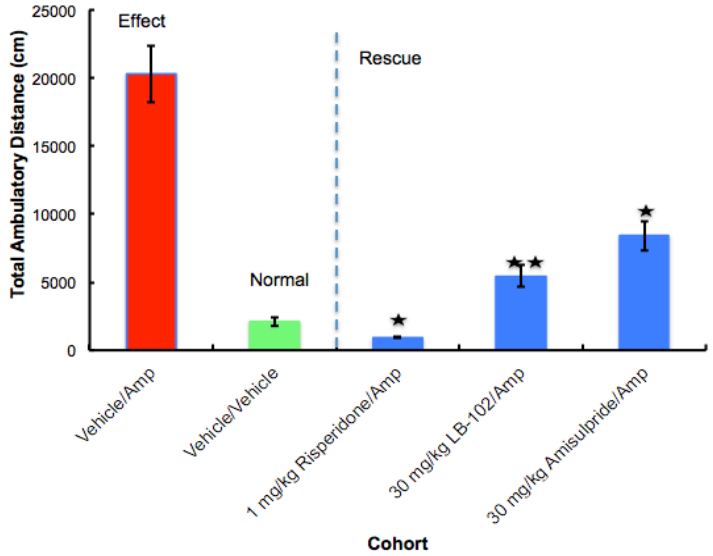
Discrimination index ((time spent exploring novel - time spent exploring familiar)/total exploration time) ± SEM (n = 10/group)

- LB-102 restored cognitive function to PCP impaired rats in a manner comparable to Amisulpride

Study results presented as part of poster: “Pre-clinical evaluation of two novel benzamides, LB-102 and 103, for the treatment of schizophrenia”, ECNP (*European Neuropsychopharmacology*, 2017, *27 (S4)*, S922-S923)

LOCOMOTOR ACTIVITY (LMA) STUDY

- LMA is a widely published and validated animal model of hyperactivity in SCZ



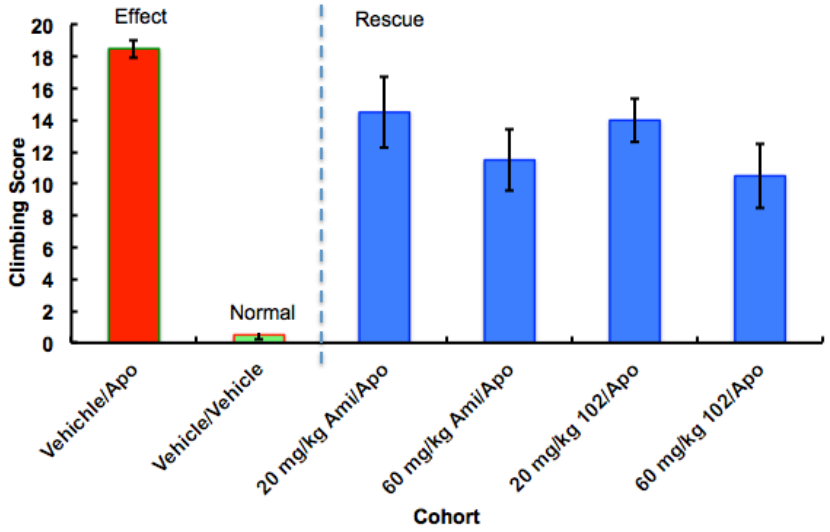
Total ambulatory distance data from an amphetamine induced LMA rat study (n=10/group) measured 6 hours post-dose amphetamine over the course of an hour. * $p < 0.01$ v control, ** $p < 0.05$ v Amisulpride

- LB-102 was statistically superior to Amisulpride in restoring normal motion to amphetamine impaired rats at 30mg/kg ($p < 0.05$)

Study results presented as part of poster: “Pre-clinical evaluation of two novel benzamides, LB-102 and 103, for the treatment of schizophrenia”, ECNP (*European Neuropsychopharmacology*, 2017, *27 (S4)*, S922-S923)

MOUSE APOMORPHINE INDUCED CLIMBING (AIC) STUDY

- AIC is a widely published and validated animal model of stereotypy in SCZ



Climbing Score± SEM (n = 10/group).

- LB-102 restored movement to apomorphine impaired rats in a manner comparable to Amisulpride

Study results presented as part of poster: “Pre-clinical evaluation of two novel benzamides, LB-102 and 103, for the treatment of schizophrenia”, ECNP (*European Neuropsychopharmacology*, 2017, *27 (S4)*, S922-S923)

IN-VIVO TOXICOLOGY CONSISTENT WITH AMISULPRIDE

RESULTS OF LB-102 NON-GLP 4 & 14 DAY TOXICOLOGY STUDIES (MPI RESEARCH)

- Initial 4 day study included groups of 6 rats (3F/3M) treated with 200, 600, 1200, and 2400 mg/kg/d LB-102
  - Rats dosed at 200 and 600 mg/kg/d survived for duration of experiment

mg/kg/dose	mg/kg/day	Survival Rate
100	200	100% survival
300	600	100% survival
600	1200	5/6 moribund, 1/6 found dead on day 2
1200	2400	5/6 died on day 2, 1/6 died on day 1

- Final results of a 14 day Dose Range Finding Study in rats produced a Maximum Tolerated Dose of 200mg/kg/d, consistent with Amisulpride
  - In excess of 7x the doses that were effective in LMA and NOR rat models of schizophrenia
- In a bar balance test, an animal model of EPS, LB-102 was indistinguishable from Amisulpride

LB-102 ANIMAL STUDY CONCLUSIONS

- LB-102 has PK profile indistinguishable from Amisulpride
- LB-102 has equivalent/superior dopamine receptor occupancy
- LB-102 displayed efficacy in three rodent models examined (2 in rats, one in mice)
  - Cognitive function, a negative aspect of schizophrenia
  - Hyperactivity, a positive aspect of schizophrenia
  - Stereotypy, a positive aspect of schizophrenia
- LB-102 efficacy in animal models comparable/superior to Amisulpride, one of the most effective antipsychotics in use today
- MTD in two week rat toxicology study showed LB-102 to be equivalent to Amisulpride

CLINICAL PROOF OF CONCEPT: PHASE 1/2A

- **Based on FDA guidance at pre-IND meeting, P1 could be done with < 30-40 healthy volunteers**
  - Single and multiple ascending doses, based on Amisulpride's known safety and PK profile
  - PK/PD/Safety endpoint
  - 200 mg/kg/d in rats equivalent to ~3X typical human Amisulpride dose (800 mg/d)
  - Start to finish time could be < 3 months
- **Phase 2a POC study,** acute schizophrenia patients
  - PANSS at 4 weeks primary endpoint, time to hospital discharge, and dopamine receptor occupancy secondary endpoints

LB-102 SUMMARY

- LB-102 is a **novel antipsychotic** closely related to Amisulpride; PCT and US patent applications were filed in November 2017 (affording IP to 2037+)
- LB-102 has as **comparable target affinity and selectivity profile** against CNS receptors as Amisulpride
- LB-102 has a **similar pharmacokinetic profile** to Amisulpride in two species and should be suitable for oral dosing in humans
- Preliminary *in vivo* data suggests that LB-102 displays **better dopamine receptor occupancy** in rat brains
- In three well validated animal models (in two species) of SCZ LB-102 showed **similar or better efficacy** compared with Amisulpride
- IND enabling package could be complete in a year and first in human study before the end of 2019
- In every measure to date, LB-102 has been **as good as or better** than Amisulpride
- With similar TRx to Amisulpride in Europe, LB-102 annual sales could exceed **$1 billion**