BRIGHT MINDS

Novel Drugs for Targeted Treatment of

CNS & Neuropsychiatric Disorders

September 2024

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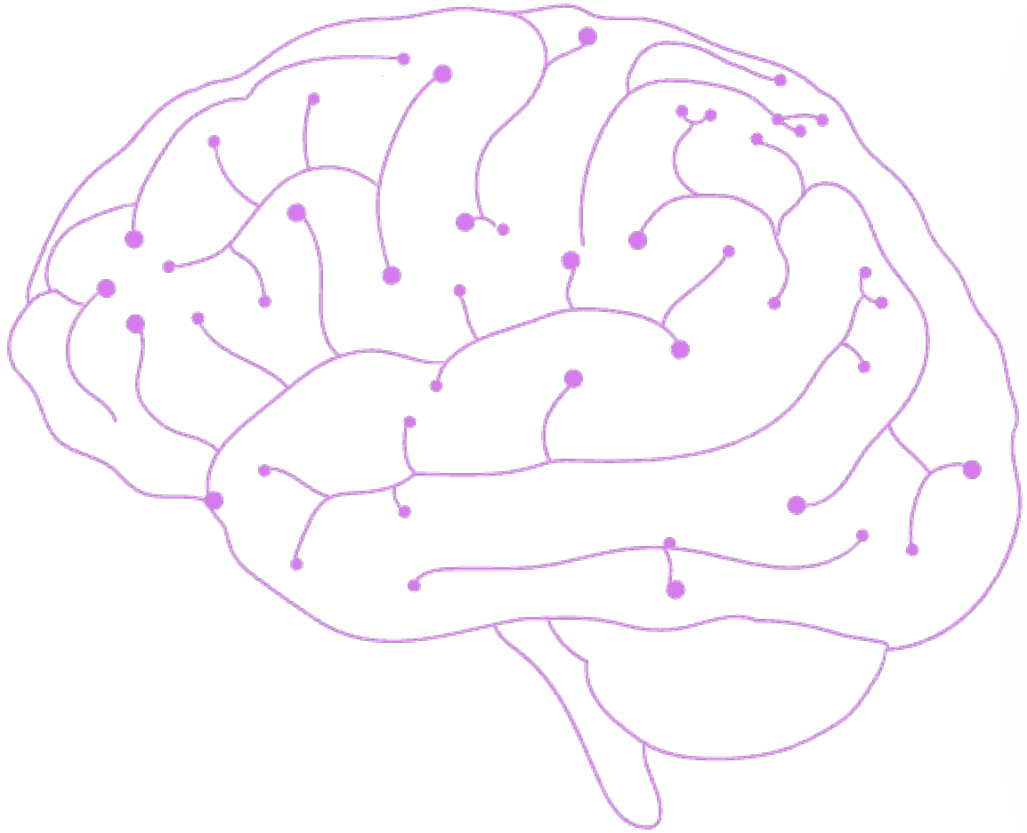
Introduction and Overview



Healing the central nervous system & brain through regulating serotonin

New approaches to neuroscience create Bright Minds

Creating New Chemical Entities That Target Serotonin Agonism

Serotonin (5-HT) is the most prominent neurotransmitter in the brain and modulates many functions

Key 5-HT_2 Receptors Targets

5-HT_{2A} Agonists

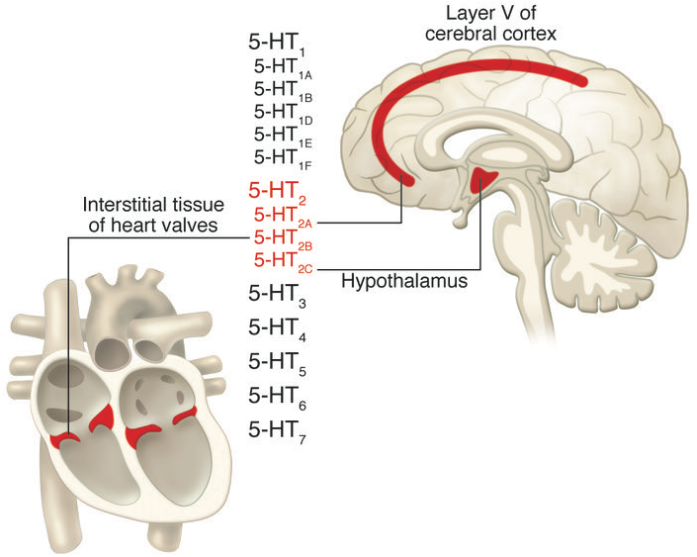
Depression, PTSD

5-HT_{2C} Agonists

Epilepsy, Impulsivity Control Disorders

$5\text{-HT}_{2A/2C}$ Agonists

Depression, Generalized Anxiety Disorder



Based on a proprietary chemistry platform Bright Minds have developed highly selective 5-HT_{2A} and 5-HT_{2C} agonists without 5-HT_{2B} activity

5-HT_{2B} activation is associated with undesirable cardiac valvulopathy

J Clin Invest. 2013;123(12):4986-4991

Leadership and scientific advisors

Ian McDonald

CEO, Director

Entrepreneur and former Investment Banker. Co-founded the company in 2017 with a group of medical chemists. Prior to Bright Minds, he led the M&A and capital markets strategy of a TSX-listed gold mining company

Jan T. Pedersen, PhD, MSc

CSO, Director

More than 25 years of expertise in neuroscience research. During 20 years at Lundbeck, he built the neurology pipeline and brought multiple programs to the clinic. Co-founder of Acadia Pharma and other biotech companies

Mark A. Smith MD, PhD

CMO

Seasoned executive in CNS drug development He has directed over 50 clinical trials across all stages. Previous experience at VistaGen and AstraZeneca

Alex Vasilkevich, MSc

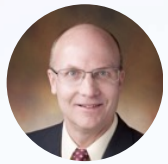
COO

Over 15 years of experience in science and pharma, supervising the development of 50+ medical and food products across multiple companies

Leading experts in Epilepsy

Joseph Sullivan, MD

Pediatric neurologist, director of the UCSF Pediatric Epilepsy Center. One of the key leaders in Dravet Syndrome research



Dennis Dlugos, MD

Professor of neurology and pediatrics at Children's Hospital of Philadelphia (CHOP) and the University of Pennsylvania School of Medicine.

Jackie French, MD

Professor of Neurology in the Comprehensive Epilepsy Center at NYU Langone School of Medicine and Founder/Director of the Epilepsy Study Consortium

Roger J. Porter, MD

Adjunct Professor of Neurology at the Univ. of Pennsylvania and Adjunct Professor of Pharmacology at USUHS; he has served as Chief Scientific Officer of the Epilepsy Foundation

Terrence O'Brien, MD

Chair of Medicine, Monash University, and Deputy Director of Research, Alfred Health. Chair of The Australian Epilepsy Clinical Trial Network

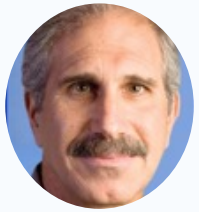
Jo Sourbron, MD, PhD

Medical doctor at UZ Ghent. Research focus on novel serotonergic compounds for drug-resistant epilepsies

Leading experts in GPCRs and neuropsychiatry

John McCorvy Ph.D

Michael P. Bogenschutz, MD



Robert C. Malenka, MD, PhD

Herbert Y. Meltzer, MD

Peter Hendricks, Ph.D

Pipeline

Rich and diverse portfolio in neurology and psychiatry with multiple programs

Lead	Features	Development Stage	Indications
5-HT$_{2C}$ agonists for CNS disorders			
BMB-101	• Selective and biased 2C agonist • Biased agonism with minimal arrestin recruitment • Suitable for chronic dosing	Clinical – Phase 2	Rare epilepsies
BMB-xxx	• Selective 5-HT$_{2C}$ agonist compound • Biased agonist	ADME/PK profiling	Obesity and feeding behaviour
Non-hallucinogenic psychoplastogens			
BMB-201	• Promotes neuroplasticity • Low or absent psychedelic activity • Devoid of 5-HT$_{2B}$ activity	IND-enabling studies	Treatment-resistant depression
5-HT$_{2A}$ agonists for the treatment of depression			
BMB-202	• Selective 5-HT$_{2A}$ "Fast-On-Fast-Off" compound • High C_{max} and short plasma half-life • 2-fold more potent than psilocin at 5-HT$_{2A}$	IND-enabling tox	Depression (Fast-onset)
BMB-xxx	• Mixed 5-HT$_{2A/2C}$ compound • 10-fold more potent than psilocin at 5-HT$_{2A}$	ADMEPK profiling	Neurology / Neuropsychiatric Indication

Epilepsy Treatment Landscape

Drug Resistant Epilepsies Remain Underserved

Drug-resistant epilepsy is still a significant issue

~30%
of Epilepsy patients develop drug resistance

Definition:
Drug-resistant epilepsy is characterized by the persistence of seizures despite the use of at least two appropriate antiseizure medications (ASMs) at effective doses

Despite the availability of over 20 ASMs, achieving seizure control in DRE patients remains difficult.

Woldman W, Cook MJ, Terry JR. Evolving dynamic networks: An underlying mechanism of drug resistance in epilepsy? Epilepsy Behav. 2019

Treatment of Drug-Resistant Epilepsies

Recent drug development focused on Dravet, LGS and other DEEs

Semah F, et al. Is the underlying cause of epilepsy a major prognostic factor for recurrence? Neurology. 1998;(51):1256-1262
Brenner T et al. Prevalence of neurologic autoantibodies in cohorts of patients with new and established epilepsy. Epilepsia. 2013;54(6):1028–1035
Image credits: UCB

Market potential

Projected US market

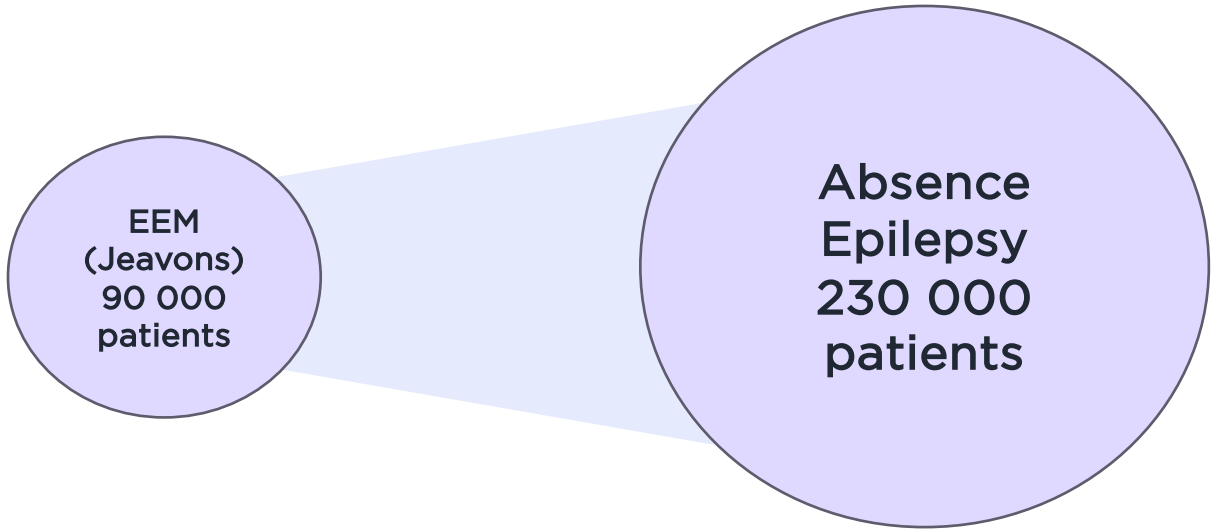
Strong IP protection until

2041*

*Including PTE extensions

Additional patent applications made to further extend market exclusivity

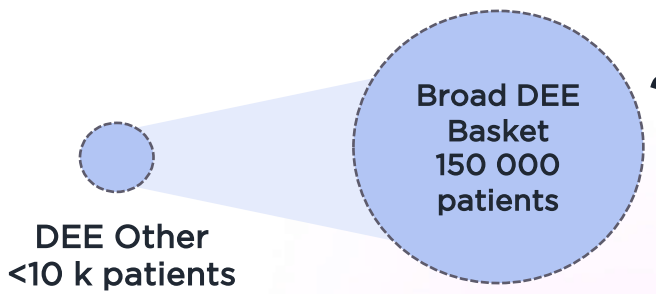
Jeavons->Absence epilepsy approach



~$2 Bn

Peak revenue potential

DEE approach



~$2 Bn

Peak revenue potential

Overcrowded drug development space

Dravet
Cannabidiol
Fenfluramine
Stiripentol
Clobazam
Topiramate
Bexicaserin
STK-001
other

LGS
Cannabidiol
Lamotrigine
Topiramate
Felbamate
Rufinamide
Fenfluramine
Bexicaserin
other

CDKL5
Ganaxolone

TSC
Epidiolex
Evirolimus
Ganaxolone

BMB-101

Novel 5-HT_{2C} Selective Agonist

Phase 2

Lead Indication

- **Drug-resistant epilepsies**

Potential Indications

- Impulsivity Disorders
- Weight Management

BMB-101 – a next-generation 5-HT_{2C} agonist for chronic treatment

Potency and Selectivity

- Very potent and selective at 5-HT_{2C} receptor
- No significant activity at other 5-HT receptors

Safety in clinical trials Phase 1

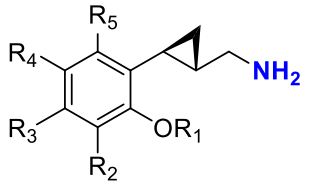
- Safe and tolerable at all tested doses
- Excellent PK/PD properties and central target engagement

Optimized for chronic treatment

- Potential for once-a-day formulation
- Designed to have sustained efficacy without tolerance

Strong IP

- CoM patent until 2036
- Possible extension to 2041



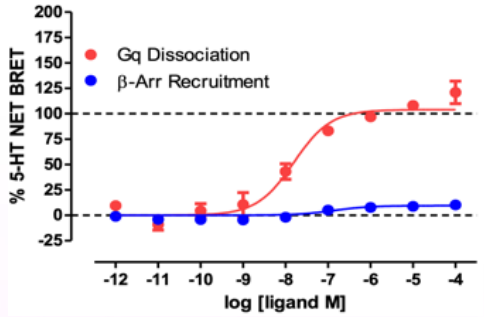
BMB-101 is uniquely positioned to address major unmet needs

Highly selective 5-HT2C agonist

Compound	5-HT$_{2A}$	5-HT$_{2B}$	5-HT$_{2C}$
BMB-101	2280	>10000	16.2
Nor-Fenfluramine	82.8	11.6	2.5
Lorcaserin	50.1	67.4	2.4
Bexicaserin	>10000	>10000	120

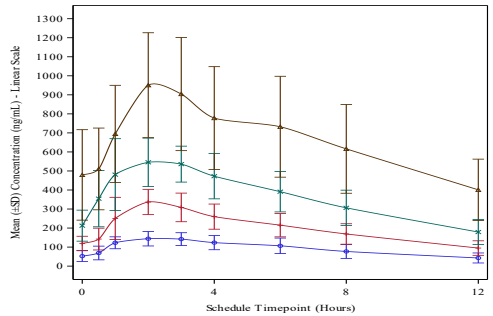
- Validated mechanism of action in DEEs
- Improved safety profile

G-protein biased agonist



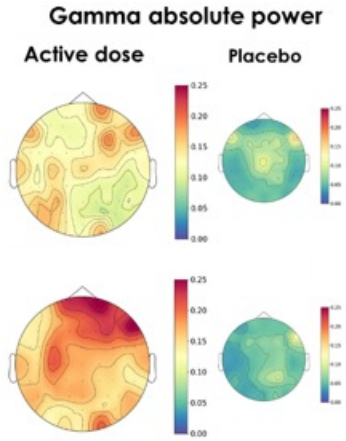
- Sustained chronic effect
- Reduced tolerance

Safety and PK/PD properties validated in Phase 1



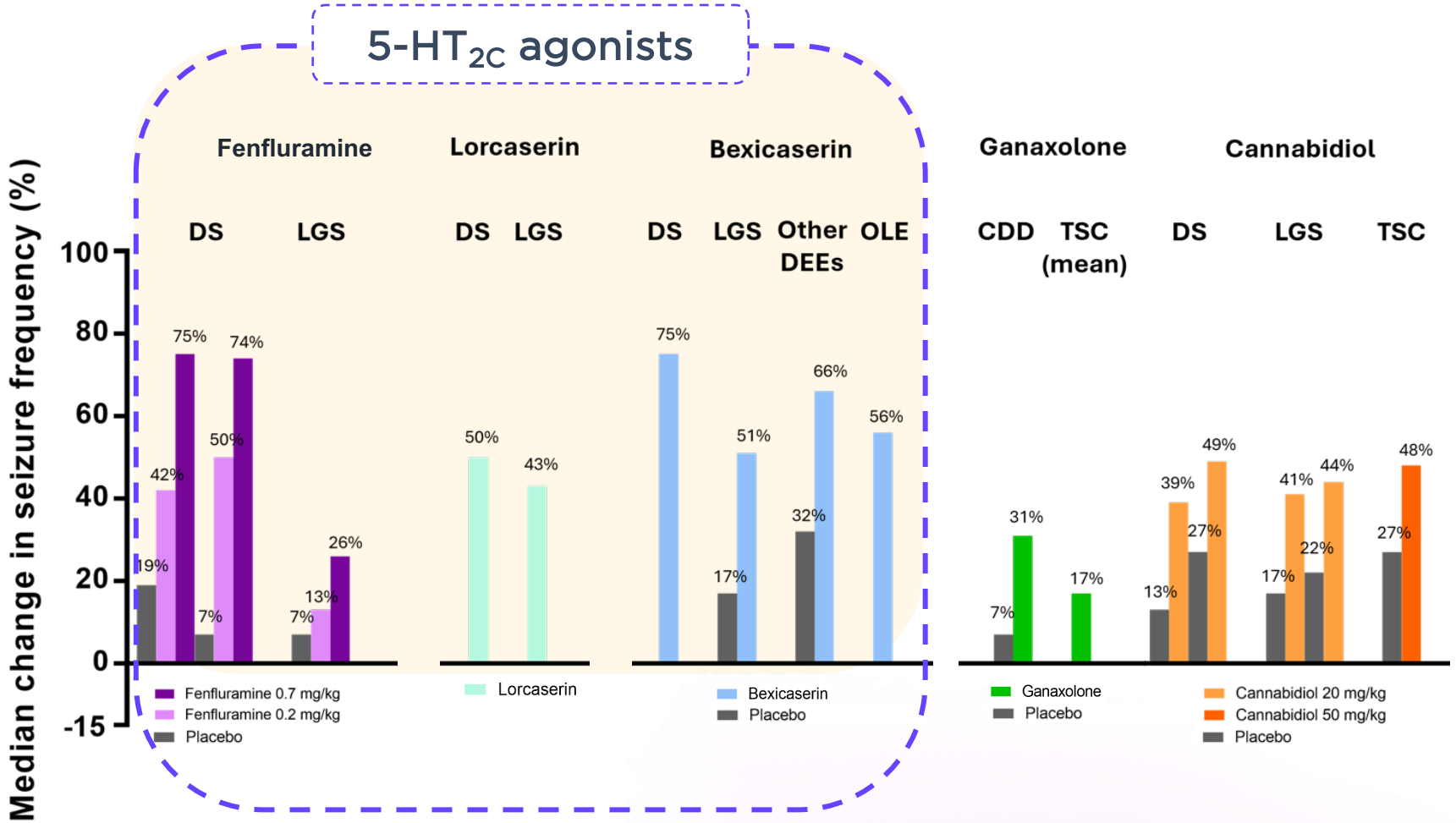
- Potential for once daily solid capsule
- Improved compliance

Proof of mechanism demonstrated in Ph.1 Increased gamma-power on qEEG



- Additional behavioral/cognitive benefits

5-HT_{2C} agonism provides superior efficacy in DEE epilepsies



DEE - Developmental and Epileptic Encephalopathy
DS – Dravet Syndrome
LGS – Lennox Gastaut Syndrome
TSC - Tuberous sclerosis
CDD - CDKL5 deficiency disorder
OLE – Open-Label Extension

Epilepsy with Eyelid Myoclonia
(also known as EEM, Jeavons Syndrome)

This is a rare epileptic disorder with high drug-resistance

Generalized epilepsy syndrome with childhood - onset (6-8 years). Other seizure types, including absence seizures and generalized tonic-clonic seizures may be present. Some patients have developmental delays. High degree of drug resistance (up to 80%). Accounts for 1.2%–2.7% of all epilepsy cases

Clinical features

Defining symptom of Jeavons syndrome involves involuntary twitching, flickering, or fluttering of the eyelids, often accompanied by upward rolling of the eyeballs and a slight backward movement of the head. The sensitivity to light is a key diagnostic feature and is more pronounced than in other forms of photosensitive epilepsies.

Role of 5-HT_{2C} agonists

The potential antiseizure effects of Fenfluramine were initially observed in patients with photosensitive epilepsy in the 1980s by Aicardi and Gastaut. Fenfluramine was effective in a subset of Jeavons Syndrome called Sunflower Syndrome (Geenen, 2021 and Patel, 2023).

No cure

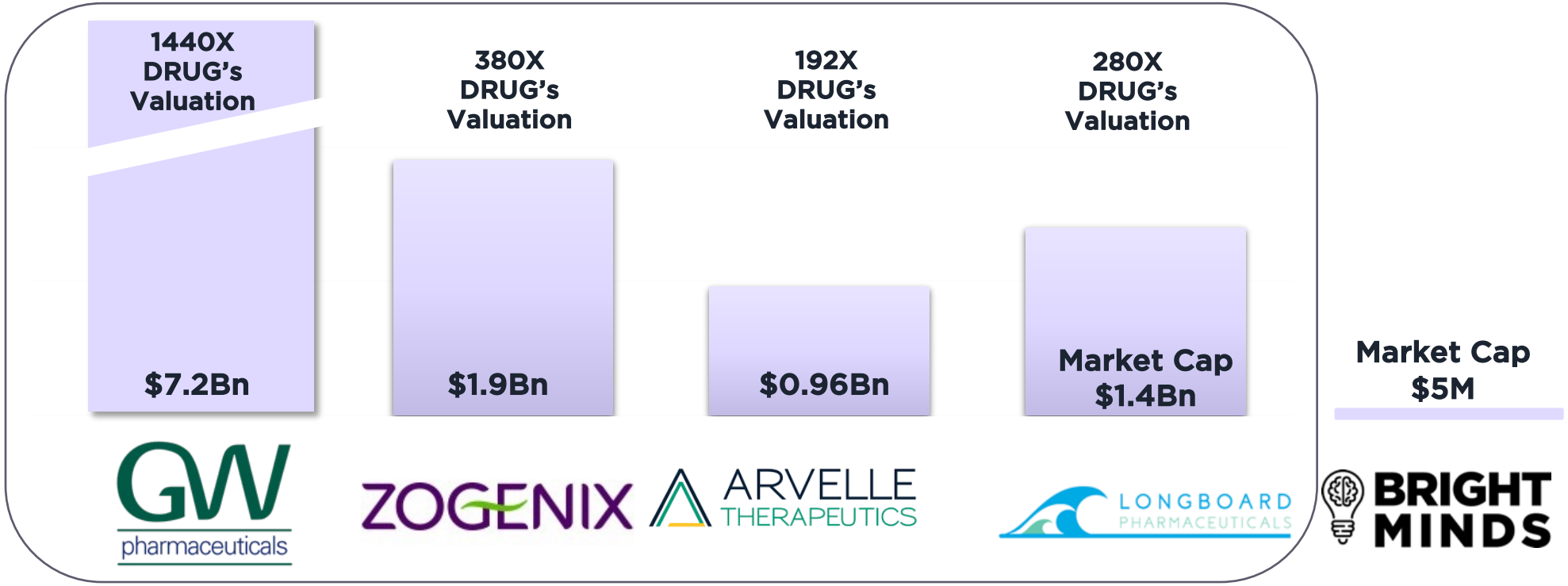
There are no approved treatments. High degree of drug resistance (up to 80%). First line of treatment includes valproate, levetiracetam, lamotrigine. Second line includes Ethosuximide, clobazam. CBD even worsens seizures in EEM patients. Sodium channel blockers should be avoided.

https://cureepilepsy.org/understanding-epilepsy/epilepsy-basics/jeavons-syndrome/

BMB-101 – Novel scaffold 5-HT_{2C} agonist

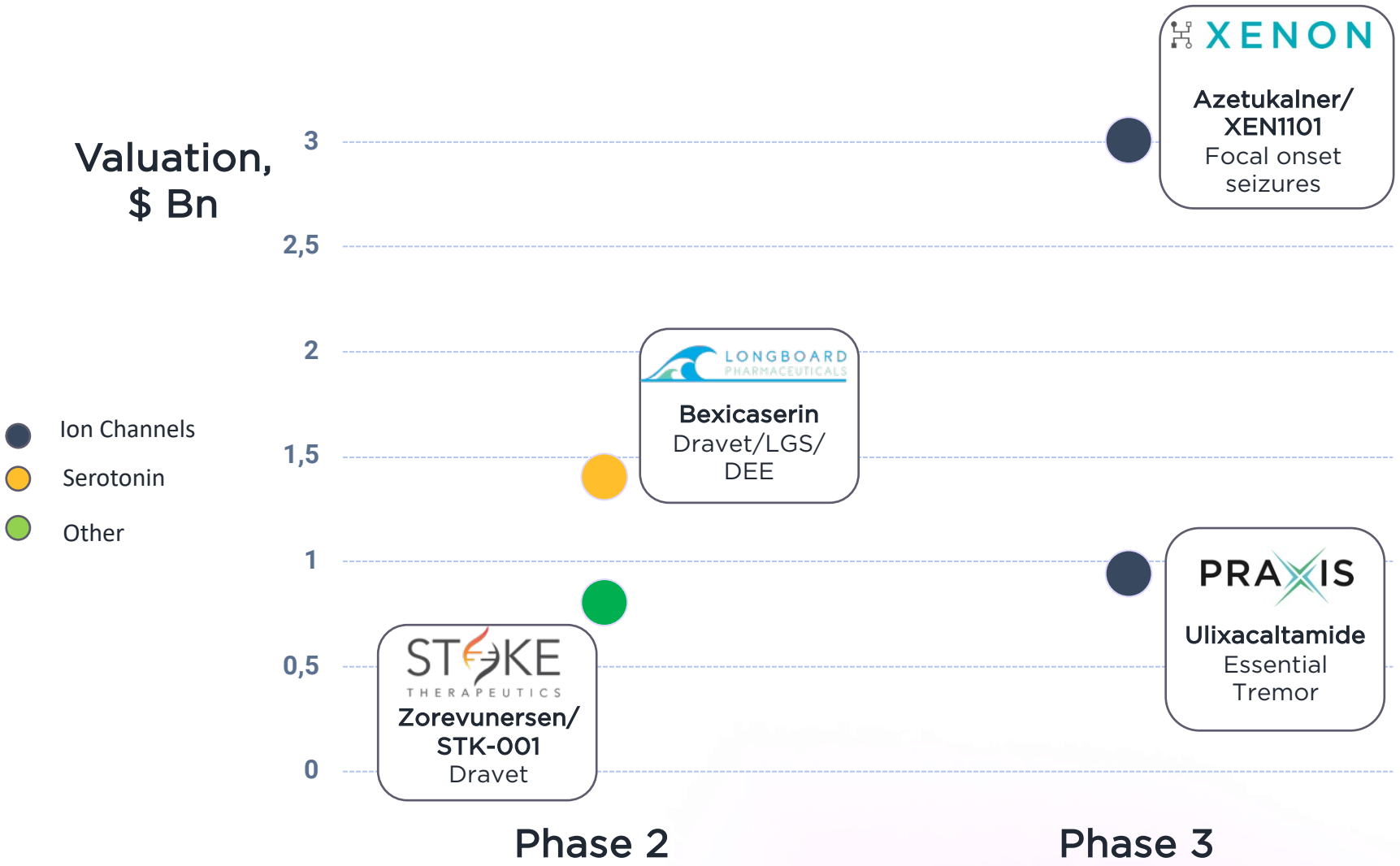
	BMB-101	Lorcaserin	Fenfluramine/ Norfenfluramine	LP352/ Bexicaserin
Lack of 5-HT_{2B} liability *(related to cardiac toxicity)*	✓	✓	x	✓
5-HT_{2C} Biased Agonism *(Sustained efficacy)*	✓	x	x	x
No 5-HT_{2A} Dose limiting effects	✓	x	x	✓
Can be Dose-optimized	✓	x	x	✓
Increased Frontal Gamma power on qEEG	✓	Not reported	Not reported	Not reported
Dosing	Once/Twice daily	Twice daily	Twice daily	Three times daily
Development Stage	Phase 2	Phase 3	Approved	End of Phase 2
Indications	EEM/DEE→ Absence Epilepsy	Dravet Syndrome	Dravet Syndrome LGS	Dravet Syndrome/LGS → Broad DEE

Undervalued relative to rare epilepsy peers



Transaction Value	$7.2Bn	$1.9Bn	$0.96Bn	$1.4Bn M CAP	$5M M CAP
Indication	Epidiolex (Childhood-onset epilepsy)	Fintepla (Dravet syndrome)	Cenobamate (Focal seizures) - EU Rights	Bexicaserin DEE basket	BMB-101 Absence/DEE basket
Date of Transaction	May, 2021	March, 2022	January, 2021	Public - NASDAQ:LBPH	Public - NASDAQ:DRUG
Stage of Development	Marketed	Marketed	Marketed	End of Phase 2	Initiating Phase 2
Acquirer Name	JAZZ Pharmaceuticals	UCB	Angelini Pharma		

Biotech Companies in Rare CNS



Recent deals in 2023:

- **Karuna 14B** by **BMS** (Multiple CNS)
- **Cerevel 8.7 Bn by Abbvie** (Schizophrenia/Epilepsy/ Parkinson's)

Next Generation Psychedelics

Novel 5-HT_{2A} | 5-$HT_{2A/2C}$ Agonists

(Candidate Profiling; IND enabling Studies Ongoing)

Lead Indication Depression

Pharmacotherapy in Depression

SSRIs

Widely prescribed, easy to use and cheap options with slow onset, limited efficacy and a number of side effects

Psilocybin, MDMA, LSD (1st generation psychedelics)

Infrequent dosing (e.g. 1-2 doses) demonstrate high efficacy with quick onset of action. Symptoms easen up for up to 12 months. Therapies expected to be very costly and labor intensive in the clinical settings under supervision. Will be approved in the coming years

Ketamine – approved in 2019

Improved efficacy and faster onset of action
But low duration of effect, potential for abuse and limited availability

2nd generation psychedelics

High efficacy, selectivity and durable effect
Reduced "trip time" and improved safety profile as compared to 1st gen psychedelics.
Reduced treatment burden and improved safety
Non-supervised or virtual supervision

Novel Approach to Next Generation Psychedelics

Key Problems with First Generation Psychedelics

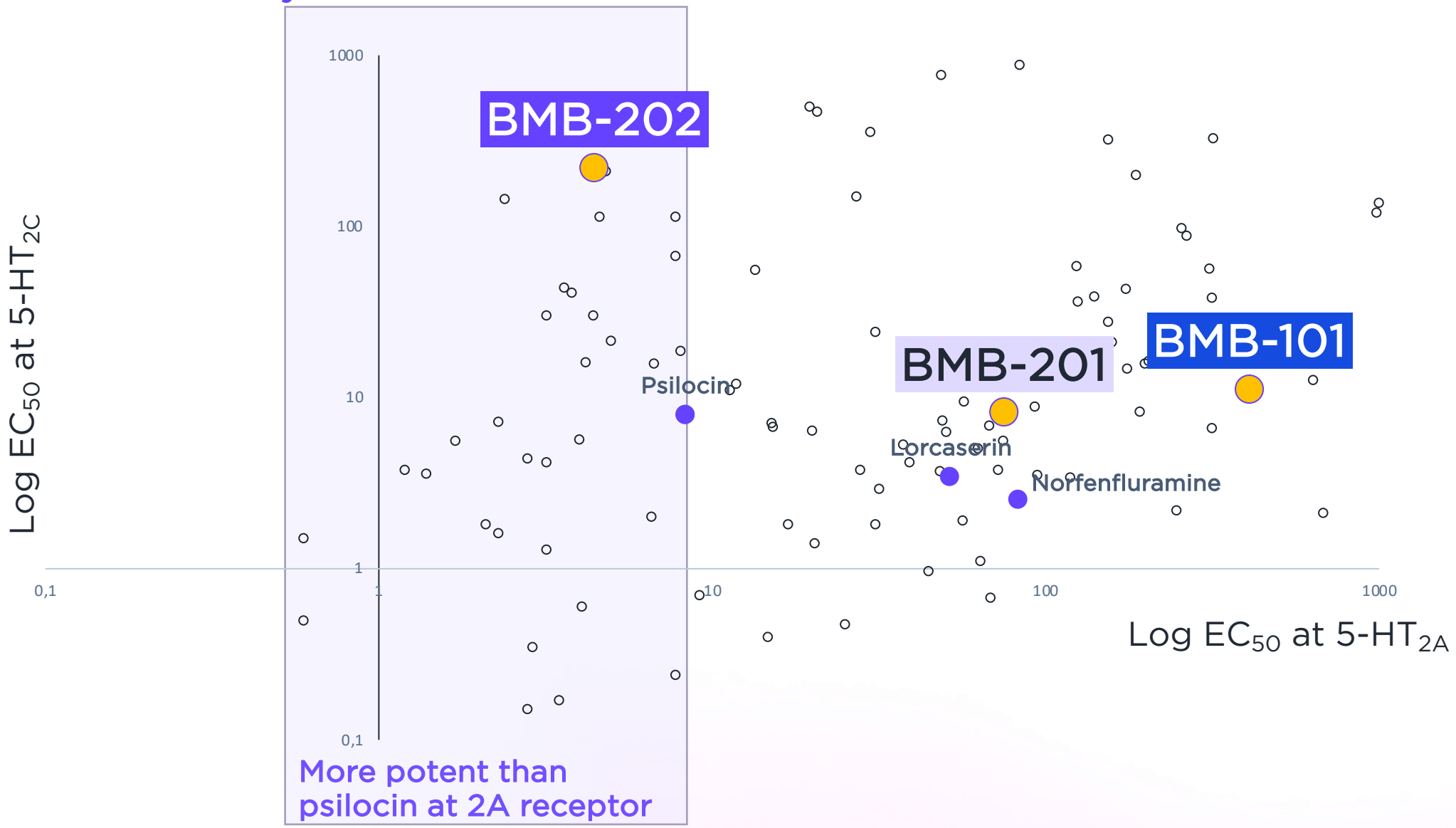
- Currently marketed drugs are active at all 5-HT receptors, including 5-HT_{2B}, which carries cardiovascular risk and restrictive REMS (Risk Evaluation and Mitigation Strategies)
- Abuse potential due to affinity towards dopamine receptors and neurotransmitter transporters
- Dissociative experience aka “Trip Time” is too long and unpredictable needing prolonged supervision. Current therapies are extremely care-intensive
- No defensible IP (no barrier to entry)

Vision/Solution for Next Generation Psychedelics

- Drugs that are selective agonists for 5-HT_{2A} and 5-HT_{2C} without 5-HT_{2B} agonist activity. Reduced activity at Dopamine receptors and neurotransmitter transporters.
- PK optimized for reliable shorter half-life and manageable “Trip Time”
- NCEs. Strong pipeline with strong IP across the 3 5-HT_{2A} chemotype (tryptamines, phenethylamines, azepinoindoles)

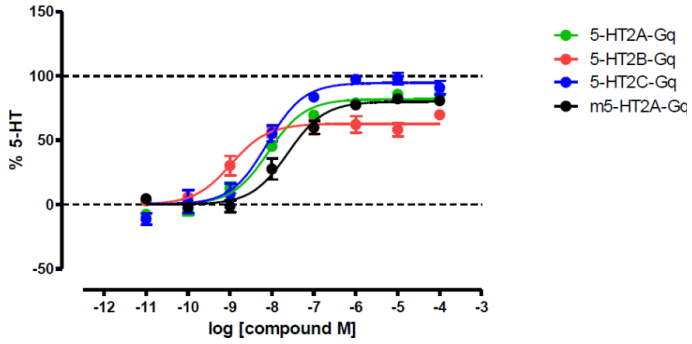
Exquisite selectivity in BMB programs

without 2B activity

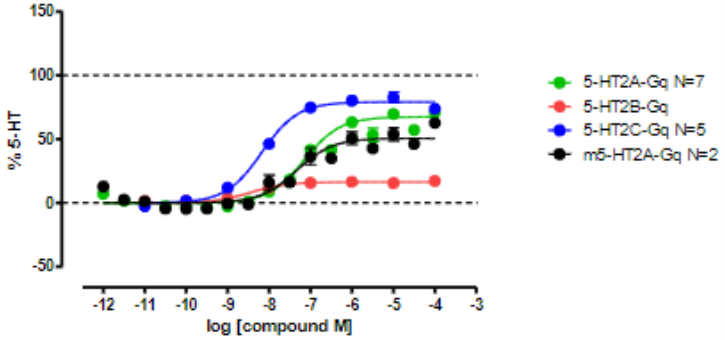


BMB-201 and BMB-202 vs Psilocin

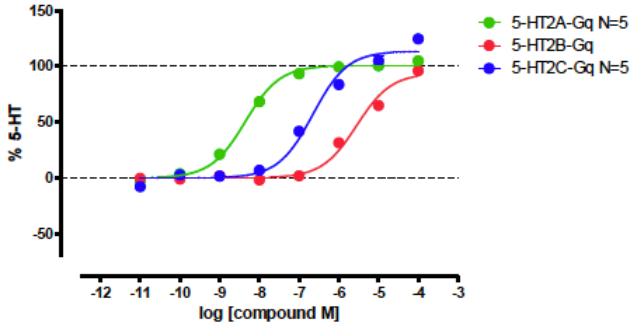
Psilocin



BMB-201



BMB-202



Compound	5-HT_{2A}	5-HT_{2B}	5-HT_{2C}
	EC_{50}, nM (Emax, %)	EC_{50}, nM (Emax, %)	EC_{50}, nM (Emax, %)
Psilocin	8.3 (82%)	1.1 (63%)	7.8 (95%)
BMB-A39a	71.2 (68%)	-	6.7 (79%)
BMB-202	4.4 (101%)	2827 (94%)	222.5 (113%)

- No significant 5-HT_{2B} activity
- BMB-201 is less potent than psilocybin/psilocin;
- BMB-202 is the most selective 5-HT_{2A} agonist known so far

BMB-202 and 201 – potential for best in class

BMB-202

The most selective 5-HT_{2A} agonist in development*

Science

- ✓ Designed to have short psychoactive effects time
- ✓ ADMEPK profiling completed
- ✓ Durable effects in rodent models of depression and anxiety
- ✓ Proprietary NCE

Vision on therapy

Short trip time (<2 hours) and short supervision time in clinics
Designed for Infrequent use

BMB-201

Potent inducer of neuroplasticity

Science

- ✓ Designed to have minimal or absent psychoactive effects
- ✓ ADMEPK profiling completed
- ✓ Efficacy in rodent models of depression, anxiety, pain, substance use disorder
- ✓ Proprietary NCE

Vision on therapy

Supervision in clinical settings is not needed
Designed for chronic use

*Based on publicly available information as of September 2024

BRIGHT MINDS

Thank you