GABA Therapeutics, Inc. – October 2025

GRX-917 - Next-Generation Anxiety Treatment

gaba THERAPEUTICS

GRX-917 Potential First-Line Anxiolytic

- GRX-917 is a superior treatment for anxiety
- De-risked development program, with high probability of success
- NDA in GAD by 2028 ($2.5B peak revs)
- Strong IP with composition of matter patents through 2042 (US)

De-Risked Program

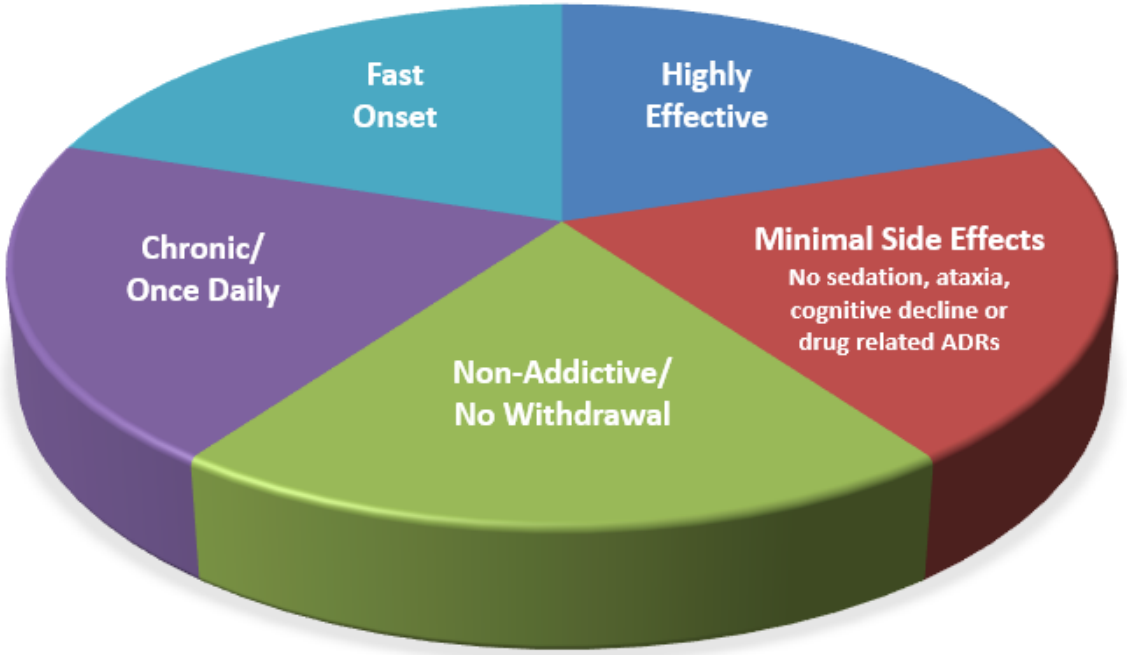
GRX-917 is an improved analog of an approved anxiety medication

✓	**Target Engagement**
✓	**Pharmacokinetics (PK)**
✓	**Safety**
✓	**Efficacy**
✓	**Commercial Differentiation**

GRX-917 Target Product Profile in Anxiety

- **Optimal Efficacy**
  - Rapid-onset and efficacy superior/comparable to Xanax® & Ativan®
- **Minimal Adverse Events**
  - No sedation
  - No ataxia
  - No cognitive impairment
  - No addiction liability
- **Once Daily, Chronic Dosing**

"A Fast and Effective Anxiolytic for Chronic Use"



GRX-917 is Deuterated Etifoxine

Same profiles except for improved PK

Stresam®

Etifoxine

Three times daily (TID)

- Safe & effective anxiolytic
- Approved in France 1979 (IP expired 80s)
- Prescribed >50% of new anxiety patients[1]
- 100+ published studies
- ETX will never compete with GRX-917 in any other major market (no IP protection)

Same safety & efficacy

GRX-917

Deuterated etifoxine

Once daily (QD)

- Same safety, efficacy, MOA
- Improved PK and dosing
- Improved compliance expected

[1] Rosenblatt interviews with etifoxine high prescribers (GABA VDR Rosenblatt PMR Research)

Deuterium Switch Strategy Has a Strong Track Record of Success

Multiple blockbuster deuterated therapeutics

Successful Outcomes from Deuterated Products

teva
Austedo (deutetrabenazine) 6 mg, 9 mg, and 12 mg tablets
~$1.6B[1]
2024 est.

Bristol Myers Squibb™
SOTYKTU™ (deucravacitinib) 6 mg tablets
$240M[2]
2024 est.

VERTEX
alyftrek
(Vanzacaftor/Tezacaftor/Deutivacaftor)
FDA Approved
Dec 2024

teva
AUSPEX PHARMACEUTICALS
$3.2B
2015

Otsuka
AVANIR pharmaceuticals
$3.5B
2014

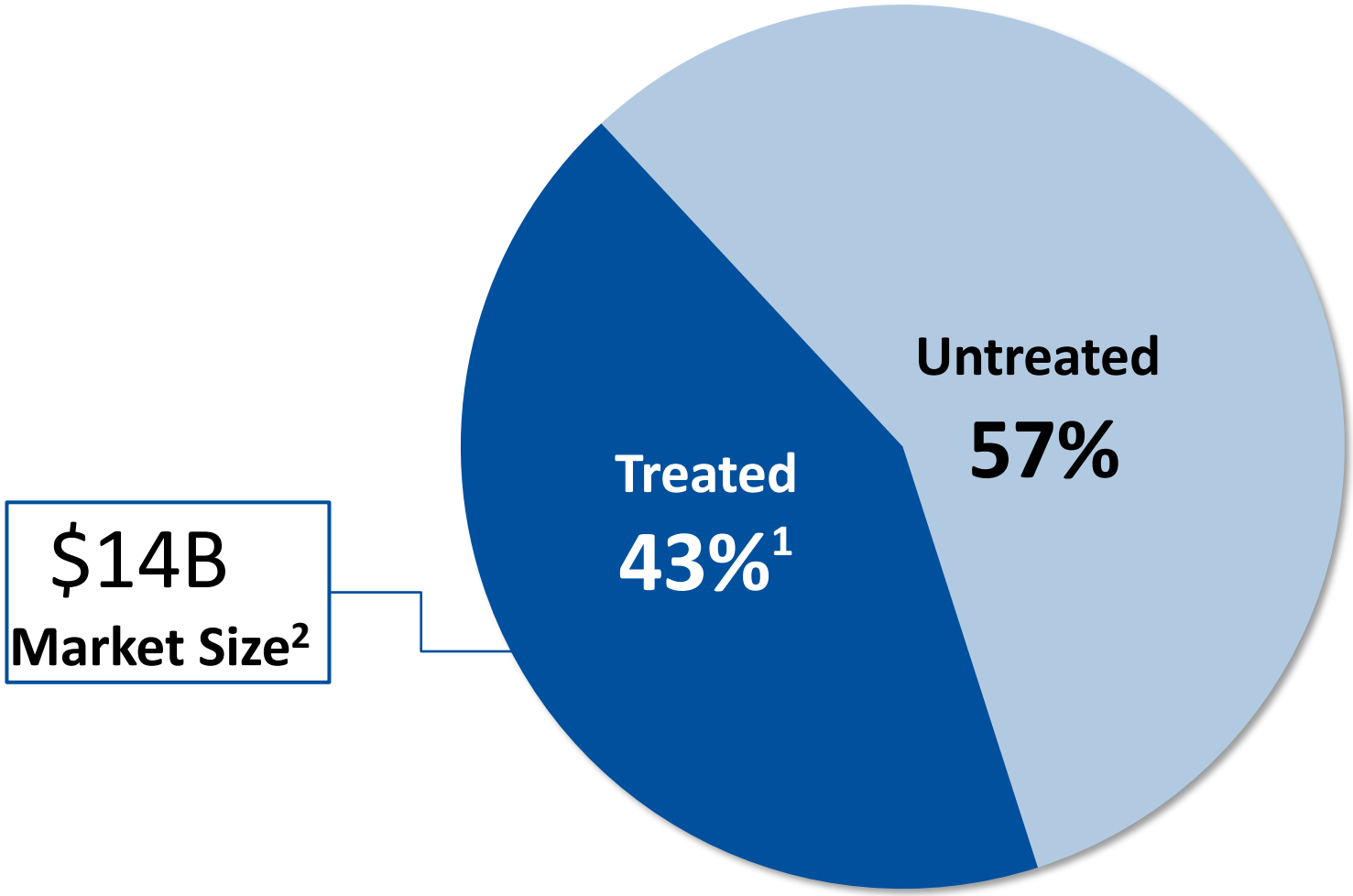
GSK
CoNCERT Pharmaceuticals Inc.®
D-atazanavir
$1B+
2009

Deuteration:

- ✓ Improves drugs
- ✓ Minimizes risk in product development

[1]Per Teva FY 2024 Guidance
[2]Per broker consensus projections (Source: FactSet)

Most GAD Patients Don’t Receive Treatment due to Poor Tolerability and Lack of Effect of Available Therapies



[1]Anxiety and Depression Association of America (2024)
[2]Global Anxiety Market: IMS, per Foster Rosenblatt Market Research

GRX-917 vs. Current Available Treatments

Key Attributes	GRX-917	SSRIs/SNRIs	Benzodiazepines
Rapid Onset	✓	4-8-week delay	✓
Efficacy	✓	Inferior	✓
Side Effects	✓	GI, sexual dysfunction, insomnia, weight gain	Sedation, ataxia, impaired cognition
Addiction Liability	✓	✓	X
Chronic Usage	✓	✓	X

Etifoxine Efficacy: Comparable to Xanax® and Ativan®

Etifoxine Study Result	Etifoxine Clinical Study	N	Reference	Date
Superior efficacy to Clonazepam (Klonopin®)	(P4) ETX vs Clonazepam (Klonopin®)	179	Vicente[1]	2020
Superior efficacy to Phenazepam	(P4) ETX vs Phenazepam	90	Aleksandrovsky[2]	2010
Superior efficacy to Buspirone	(P4) ETX vs Buspirone	170	STRETI S.226/GB	1998
Comparable onset and efficacy to Alprazolam (Xanax®)	(P3) ETX vs Alprazolam (Xanax®) Marketing Authorization in India 2024	260	Prabhakar et al (2024)[3]	2024
Comparable onset and efficacy to Alprazolam (Xanax®)	(P4) ETX vs Alprazolam (Xanax®)	202	ETIZAL S.650/EN	2015
Comparable onset and efficacy to Lorazepam (Ativan®)	(P4) ETX vs Lorazepam (Ativan®)	191	ETILOR S.392/EN	2006

1. Vicente et al., Psychopharmacology 237, 3357–3367 (2020)
2. Aleksandrovsky et al., Russian Psychiatric Journal;Therapy of the mentally ill; No. 1; 74-78 (2010)
3. Prabhakar et al. Role of Etifoxine in Generalized Anxiety Disorder: a phase III randomized, double-blind, double-dummy, active-controlled study in India. Neuroscience Applied, Vol 3, Supplement 2, 104122 (2024).
Note – GABA management is not aware of any other region where this approval process is available.

Etifoxine Safety: Excellent

Safety	Comment	Source
Non-Addictive	"No cases of abuse, misuse or pharmacodependence."	Cottin et al[1] (based on +15M Rx)
No Sedation	No effects on vigilance or psychomotor performance	Micallef et al[2]
No Impaired Cognition	No effect on alertness or other cognitive parameters in elderly	Deplanque et al[3]

No Serious Adverse Events	Very rare ADRs found in a PV database of etifoxine are not drug related:
	• Incidence rates < 1 per million
	• Never reported in any clinical trial of etifoxine (per EMA) or GRX-917
	• Former FDA Director Psych Products advised:
	  • No reason to assume causation
	  • FDA will not refer to the etifoxine label
		PV Analysis of Etifoxine Serious ADRs in EudraVigilance Database[4]

Table of Etifoxine Serious Adverse Events from All Controlled Clinical Trials

System Organ Class (SOC) MedDRA PT	Etifoxine hydrochloride	Blinded	Active comparator	Placebo
Ear and labyrinth disorders	**0**	**0**	**1**	**0**
Vertigo	0	0	1	0
Eye disorders	**0**	**0**	**1**	**0**
Retinal artery thrombosis	0	0	1	0
Hepatobiliary disorders	**1**	**0**	**0**	**0**
Jaundice	1	0	0	0
Injury, poisoning and procedural complications	**1**	**4**	**1**	**1**
Contusion	0	1	0	0
Ligament injury	1	0	0	0
Ligament sprain	0	1	0	0
Overdose	0	0	1	0
Road traffic accident	0	1	0	0
Wound	0	1	0	0
Injury	0	0	0	1
Musculoskeletal and connective tissue disorders	**0**	**0**	**1**	**0**
Back pain	0	0	1	0
Neoplasms, benign malignant and unspecified (incl cyst)	**1**	**0**	**0**	**0**
Fibroma	1	0	0	0
Nervous system disorders	**0**	**0**	**1**	**0**
Somnolence	0	0	1	0
Psychiatric disorders	**0**	**0**	**1**	**0**
Suicidal ideation	0	0	1	0
Surgical and medical procedures	**1**	**0**	**0**	**0**
Cervical conisation	1	0	0	0
TOTAL	**4**	**4**	**6**	**1**

Source: EMA/CHMP Etifoxine Assessment Report, Jan 2022

1. Cottin et al., Fundamental & Clinical Pharmacology 30 (2016) 147–152
2. Micallef et al., 2001 Blackwell Science Fundamental & Clinical Pharmacology 15 (2001) 209-216
3. Deplanque et al., European Neuropsychopharmacology (2018) 28, 925-932
4. Kinexum-Pharmacovigilance Analysis of Etifoxine 2023-03-13

GRX-917 Phase 1 (conducted by GABA) – Evidence of Tolerability and QD Dosing

Safe, well-tolerated, with minimal adverse events

Nervous System Disorders	GRX-917 (n=75)	Placebo (n=25)
Dizziness	4%	4%
Headache	17%	12%
Paresthesia	1%	4%
Somnolence	0%	8%
Ataxia	0%	0%
Lethargy	3%	0%
Cognitive Deficit	0%	0%

GRX-917 Phase 1: A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single and Multiple Ascending Doses of GRX-917 in Healthy Adult Subjects

GRX-917 demonstrated improved PK and once-daily dosing

	Etifoxine*	GRX-917
Half-life	4 hours	>12 hours
Daily dose	200 mg	60 mg
Dosing regimen	**TID**	**QD**

*** Etifoxine Phase 1:** A Two Stage, Double-Blind, Placebo-Controlled Single and Multiple Dose Study To Evaluate The Pharmacokinetics, Pharmacodynamics, and Safety of Oral Etifoxine in Normal Healthy Volunteers

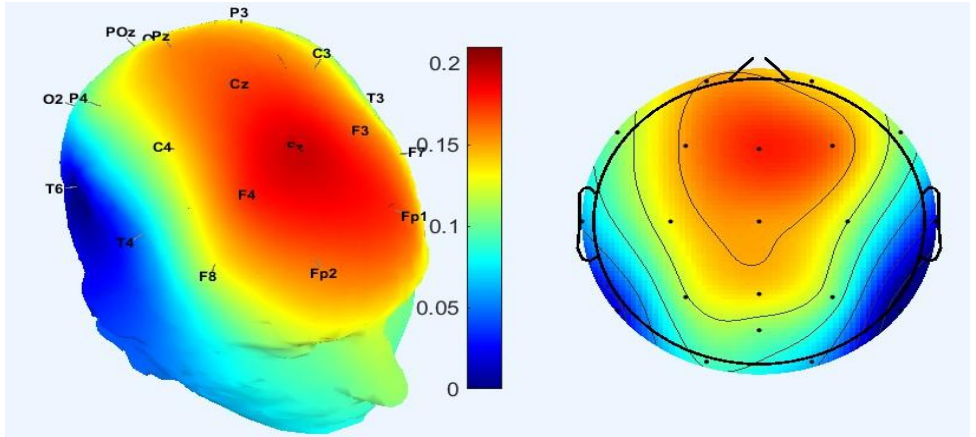
GRX-917 Increases qEEG Beta Power in Phase 1

qEEG biomarker confirms GABA-A target engagement and supports anxiolytic efficacy

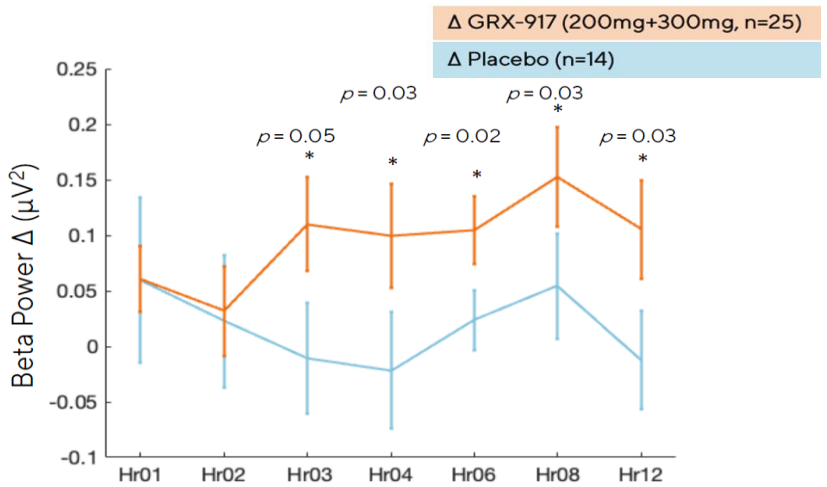
- Increased Beta Power confirms $GABA_A$ receptor target engagement
- Demonstrates exposure response (p<0.0001)
- Supports anxiolytic efficacy

- Increased Beta Power is dose- and time-dependent for at least 12 hours (p<0.05)
- Rapid onset, sustained

GRX-917 Exposure Response Heat Map (p<0.0001)



GRX-917 Increases qEEG Beta Power

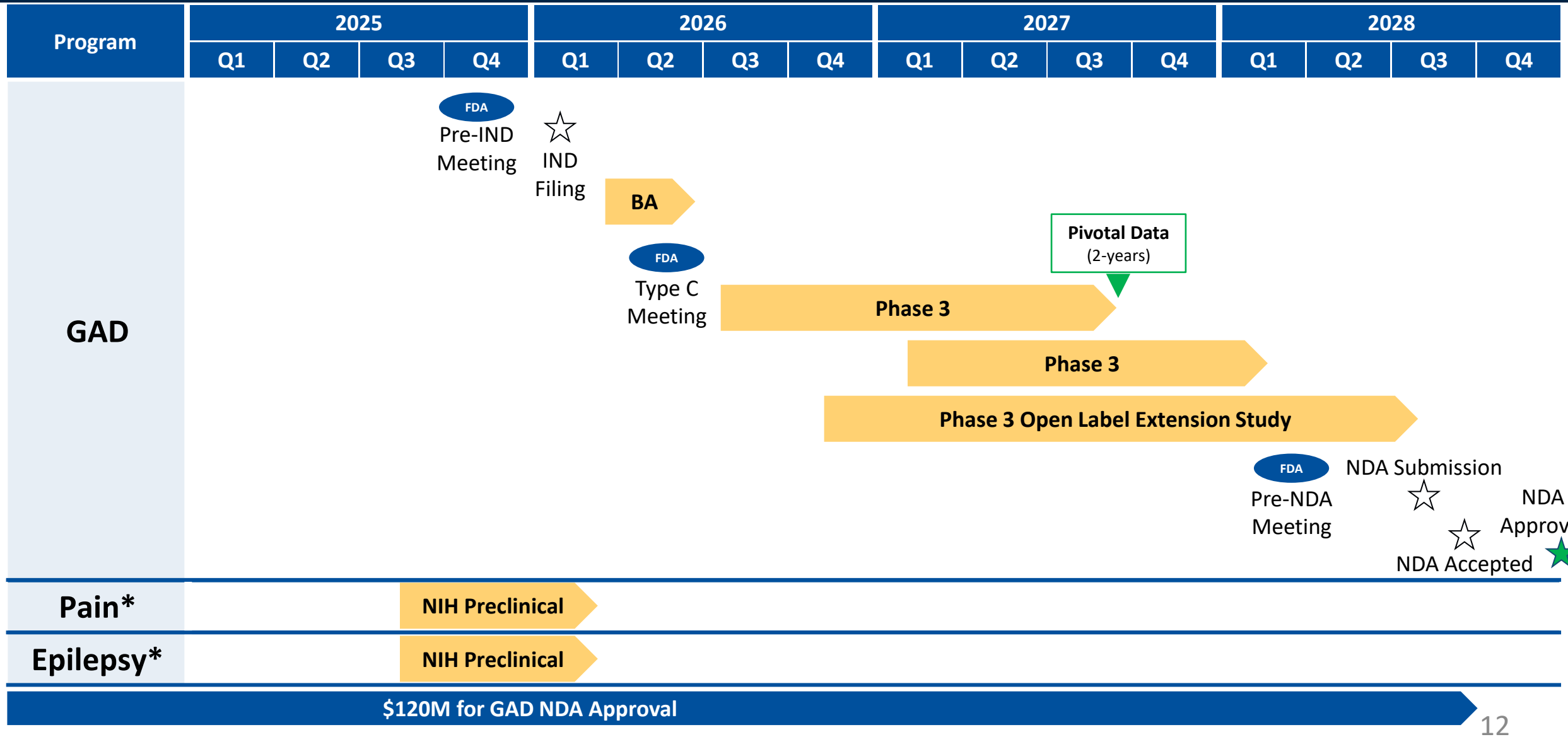


Hours (post oral dosing)

GRX-917 Phase 1: (Study GRX-917-01) - A Phase 1, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single and Multiple Ascending Doses of GRX-917 in Healthy Adult Subjects

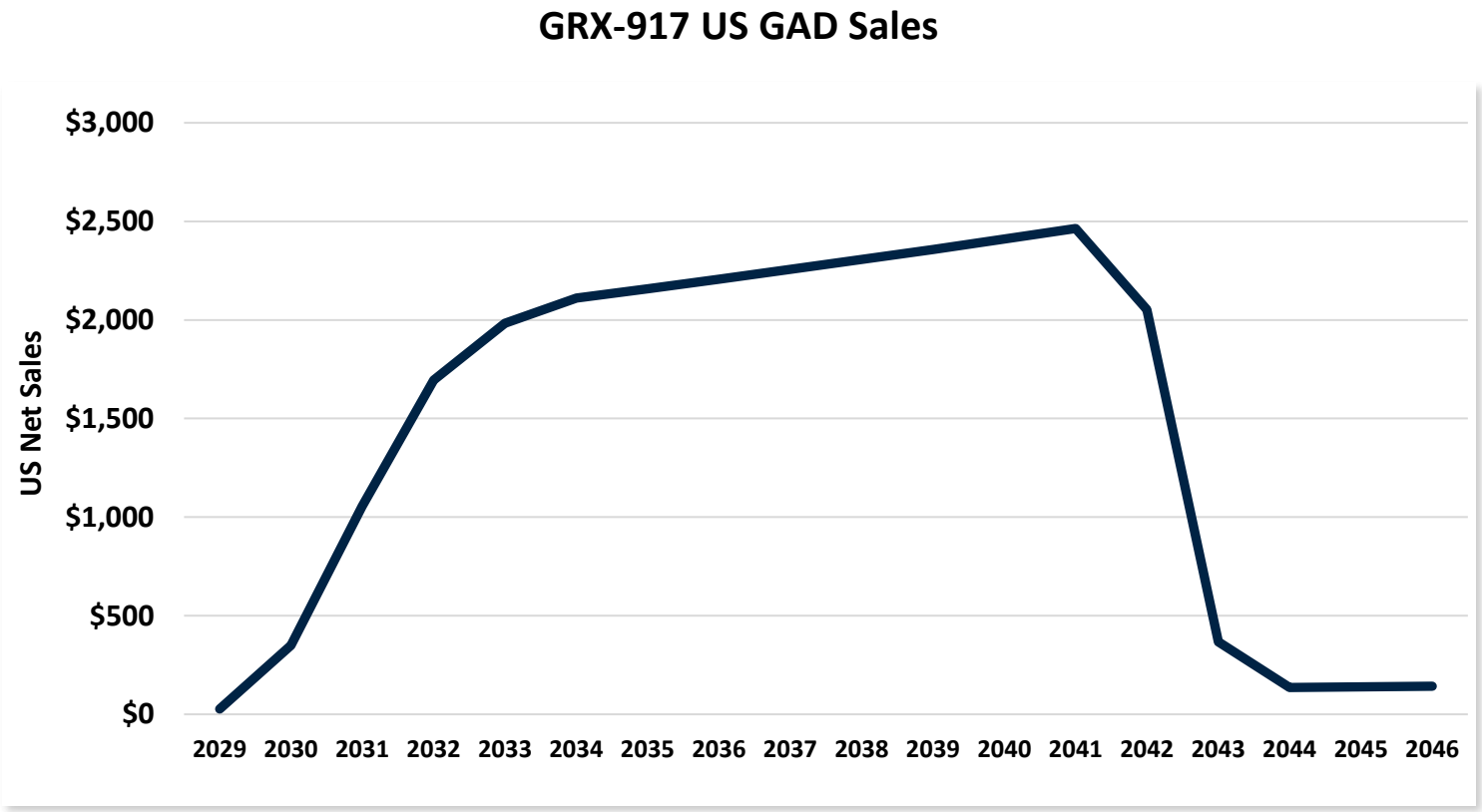
GRX-917 Core GAD Clinical Program

2-Year Inflection Point (1st Phase 3 Readout)



*NIH programs are entirely funded and executed by NIH.

GRX-917 US GAD Sales Forecast: $2.5B Peak Revs



Source: Rosenblatt Life Science

Key Forecast Assumptions

- US GAD prevalence (2029): 10.8m
- US GAD treated patients (2029): 4.9m
- GRX-917 peak penetration:
  - First line treatment: 10%
  - Uncontrolled patients: 20%
- GRX-917 peak patients on drug: 653k
- Average Rx per year: 4.7
- GRX-917 gross price per Rx: $623 at launch increasing 1.5% per year
- Gross to net discount: 30%
- US peak revenue: $2.5B
- Gross margin: 90%

Intellectual Property Overview: Global CoM IP Potentially through 2046

Country	Date Applied	Application number	Status of the application	Publication No.	Publication date	Grant No.	Date of grant
Australia	2017-09-20	AU2020201728	Granted	AU2020201728A1	2020-03-26	AU2020201728B2	2021-12-23
Australia	2017-09-20	AU2016235495	Granted	AU2016235495A1	2020-05-14	AU2016235495B2	
Brazil	2017-09-20	BR112017020081-3A	Granted	BR112017020081A2	2018-05-06	BR112017020081B1	2021-11-30
Canada	2017-09-20	CA2979853A	Granted	CA2979853A1	2016-09-29	CA2979853C	2021-05-11
China	2017-09-20	CN201680028306.5	Granted	CN107530323A	2021-05-04	CN107530323B	2021-05-04
Europe	2017-09-20	EP16769437.1	Granted	EP3347006A1	2018-07-18	EP3347006B1	2022-07-27
Validated In: AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LI, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR							
India	2017-09-20	IN201727035718	Granted	IN201727035718	2017-12-29	IN201727035718	2025-01-28
Israel	2017-09-20	IL270627	Granted	IL270627A	2019-12-31	IL270627B2	2023-03-01
Israel	2017-09-20	IL254567	Granted	IL254567A	2017-11-30	IL254567B	2020-03-31
Japan	2017-09-20	2018-500276	Granted	JP2018508592A	2018-03-29	JP6762507B2	2020-09-30
Japan	2017-09-20	2022-176234	Granted	JP2023009114A	2023-01-19	JP7376668B2	2023-11-08
Mexico	2017-09-20	MX2017011978A	Granted	MX2017011978A	2018-09-02	383647	2021-06-16
South Korea	2017-09-20	KR10-2017-7028263	Granted	KR20170137085A	2018-02-09	KR102290766B1	2021-08-19
USA	2015-03-20	62/135,979	Converted - Provisional	-	-	-	-
USA	2016-03-18	15/557,748	Granted	US20180064717A1	2018-08-03	US10,080,755B2	2018-09-25
USA	2018-09-21	16/138,509	Granted	US20190015419A1	2019-01-17	US10,736,901B2	2020-08-11
USA	2020-08-07	16/988,586	Granted	US20200405726A1	2020-12-31	US11,672,805B2	2023-06-13
USA	2023-01-05	18/141,999	Pending - Published	US20230263805A1	2023-08-24	-	-

- Robust IP portfolio with composition patent protection through at least 2036
- Potential Hatch-Waxman extensions through 2042
- New patent filings could increase IP protection through 2046

Capital Requirements and Use of Funds

$ in millions

Use of Funds	1st Phase 3 GAD	Total to NDA
IND Opening Studies	$4.5	$4.5
Clinical Trials	$19.0	$58.0
Tox & Research	$4.3	$10.6
CMC	$0.6	$18.2
Regulatory	$0.5	$2.5
G&A	$13.5	$27.7
Total	**$42.0**	**$121.0**

All costs supported by vendor quotes

Key Executives

Decades of successful leadership, clinical development, and commercialization in pharma and biotech

Mario Saltarelli, M.D., Ph.D.
Chief Executive Officer,
Director

Pfizer
Abbott
Shire
Johns Hopkins School of Medicine

Richard Farrell
Chief Financial Officer,
Director, & Co-Founder

EY
Deloitte.

Kathryn King, Ph.D.
Chief Operating Officer

Abbott
abbvie
Takeda
APTINYX

Mary Szela
Commercial Consultant

Abbott
abbvie
TriSalus Life Sciences
melinta therapeutics

David Putnam, Ph.D.
Chief Scientific Officer,
Co-Founder

Roche
ucb

Olivier Dasse, Ph.D.
Senior VP of Chemistry,
Co-Founder

ucb

Key Advisors

Highly respected leaders in pharma development, psychiatry, and regulatory

Robert Berman, M.D.
Scientific Advisory Board Chairman
Co-Founder, Biohaven

biohaven pharmaceuticals

Bristol Myers Squibb

Pfizer

Yale SCHOOL OF MEDICINE

Maurizio Fava, M.D.
Clinical & Regulatory Advisor
Psychiatrist-in-Chief
Mass General/ Harvard Med

MASSACHUSETTS GENERAL HOSPITAL
PSYCHIATRY

Thomas Laughren, M.D.
Clinical & Regulatory Advisor
Former Director, Div. Psych Products, FDA/CDER

FDA

MASSACHUSETTS GENERAL HOSPITAL
PSYCHIATRY

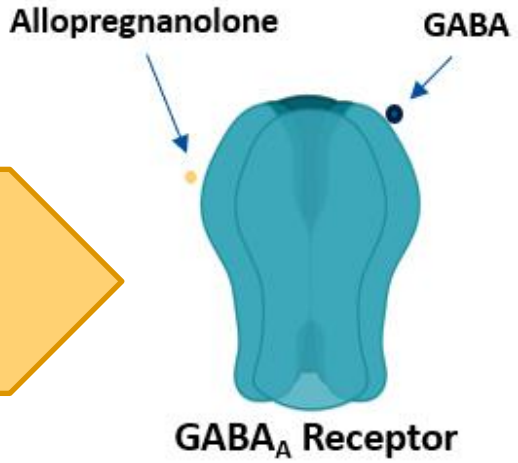
Appendix – Potential Additional Indications

GRX-917 – Induction of Endogenous Neurosteroids

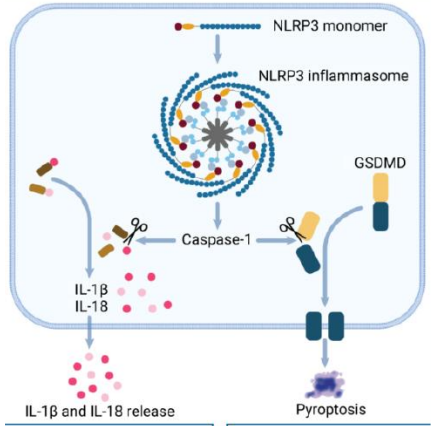
Potent neuromodulatory and anti-inflammatory activity

GRX-917/etifoxine increase neurosteroid synthesis[1]

Neurosteroids modulate receptors[2]
(anxiety, depression, epilepsy)



Neurosteroids inhibit NLRP3 inflammation[3]
(epilepsy, MS, pain, obesity)



NLRP3/IL-1beta Pathway

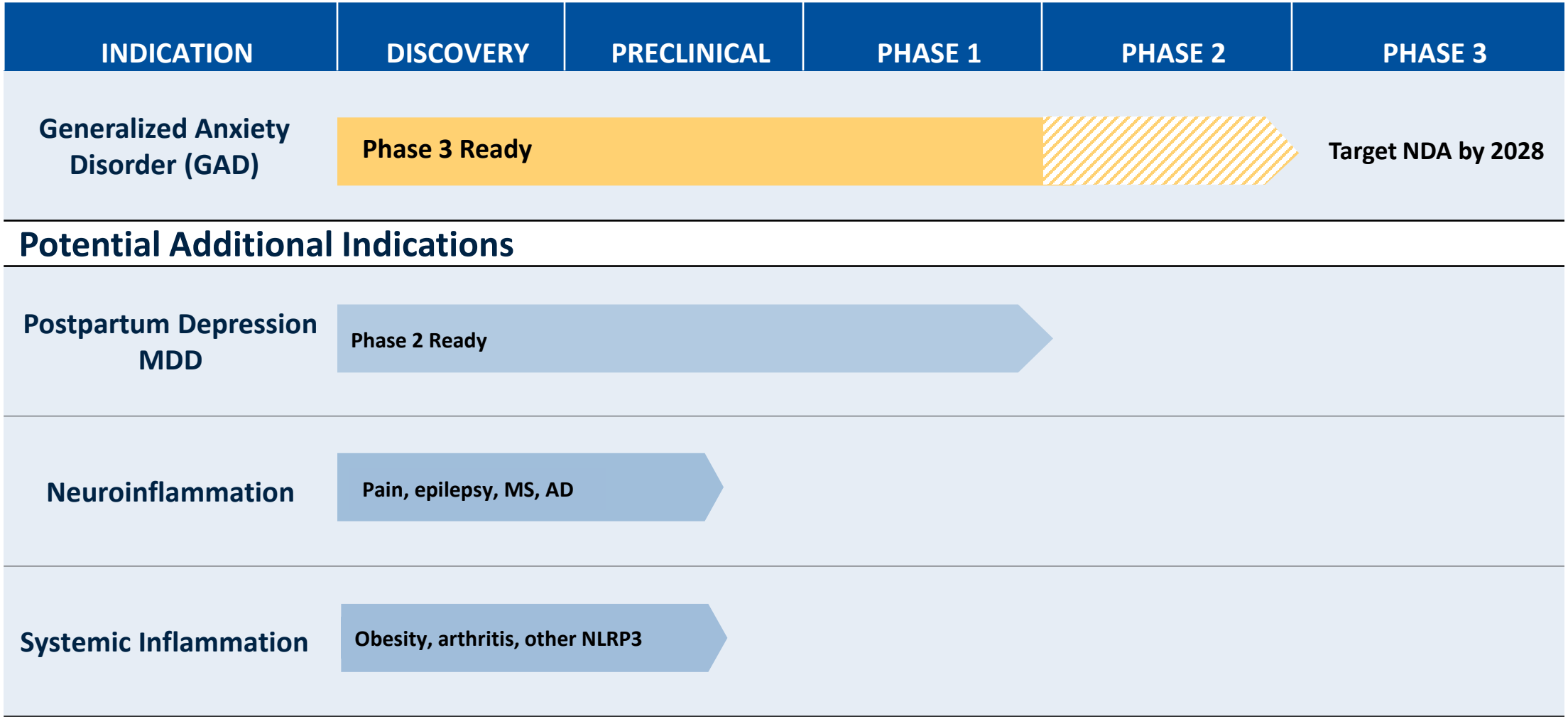
[1]do Rego JL et al (2015) PLoS ONE 10(3): E0120473 ; internal data

[2]Lambert et al (2003) Prog Neurobiol 71(1); 67-80.

[3]Osmond et al (2023)

GRX-917: Pipeline-in-a-Drug

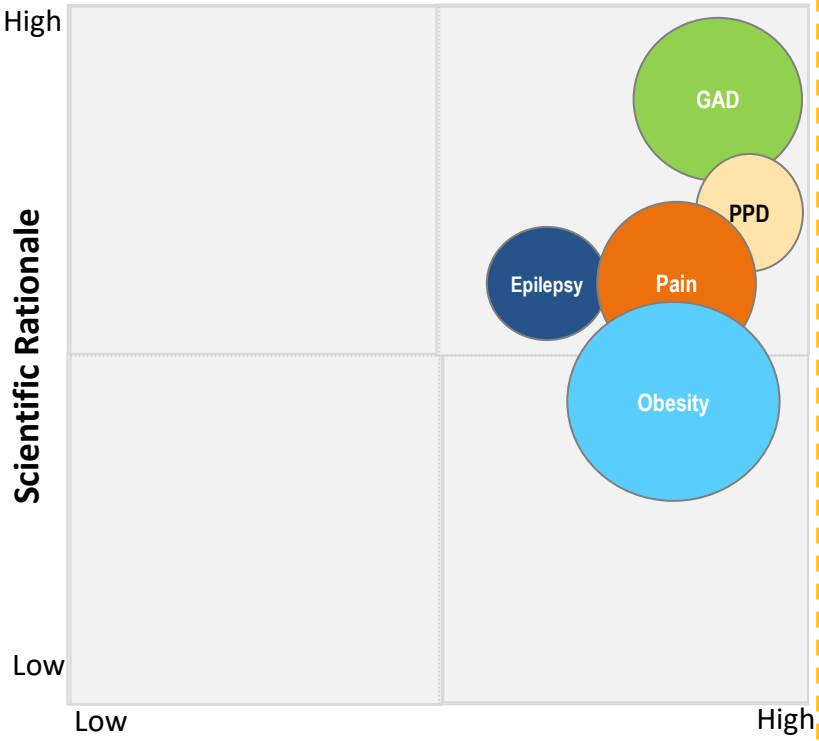
De-risked indications ready to begin clinical trials



Derisked by MOA, preclinical, and/or clinical efficacy

GRX-917 Additional Indications Strategy

Strong scientific rationale and clinical/regulatory favorability exist for multiple blockbuster indications beyond GAD
NLRP3/IL-1beta inflammation drives all GRX-917 indications



Postpartum Depression (PPD)	• Validated by MOA; ETX efficacy in GAD; zuranolone efficacy in PPD • Improved safety and chronic dosing – substantial differentiation from Zurzave • Established development and regulatory pathways
Pain	• Broad-spectrum analgesic efficacy • Non-addictive, non-opioid oral analgesic with minimal side effects • “Pipeline in a product” - efficacy in pain, anxiety, and epilepsy
Epilepsy	• Validated by ETX, ganaxolone, brexanolone, GABA-A PAM efficacy • Potential use in temporal lobe, rare, and inflammatory epilepsies • Ongoing collaboration with NIH/NINDS will confirm specific indications
Obesity	• ETX induced semaglutide-like weight loss in a mouse obesity model • Normalized inflammatory cytokines and dyslipidemia in animal models • NLRP3 MOA • Potential for monotherapy or combo therapy with GLP-1R agonists without AEs

Market size.