



Clinical-stage biopharmaceutical company focused on
epilepsy;
leader in ion channel drug discovery and development

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Saniona Investment Highlights

- Expanding pipeline in collaboration with partners - Tesofensine targeting market launch in 2024 together with partner, Tesomet (phase 2b), SAN711 (phase 2a) and SAN903 (phase 1) and several pre-clinical assets available for partnering
- Cutting-edge proprietary ion channel drug discovery engine – continuous value creation through generation of new high potential drug candidates for epilepsy and other CNS indications
- Platform validated by leading pharmaceutical companies – SEK +400m received through successful spinouts, partnerships, and licensing agreements with upside potential preserved
- Potential near-term income from partnerships - research funding from existing partnerships, potential milestones, royalty income from tesofensine, new partnering opportunities on clinical assets and platform
- Focused epilepsy pipeline addressing indications with significant medical need including SAN711 (phase 2 POC ready) for potential internal development partly financed through partnership income

Successful partnership history – platform validated by several leading pharmaceutical companies

Partnerships and spinouts

Income (SEKm)

Future Upside

2023

	R&D collaboration/license	~4	Milestones + royalties
	Joint Venture	~4	33% ownership
	R&D collaboration/license	~20	Milestones + royalties
	R&D collaboration/license	~20	Regained program
	R&D collaboration/license	~111	Regained program
	Spinout (shareholding sold)	~126	
	License (tesofensine)	~25	Milestones + royalties
	Grants	~8	
	Spinout distributed to shareholders		Milestones + royalties
	R&D collaboration/license	~16	Regained program
	Spinout + R&D collaboration	~53	Earnout + royalties

2012

	R&D collaboration/license	~17	Regained program
Total Income (SEKm)		~404	

Expanding pipeline of new drug candidates with solid scientific rationale

Product Candidate	Indication	Research	LOP/CS	Pre-clinical	Phase 1	Phase 2a	Phase 2b	Phase 3	Comment	
Tesofensine	Obesity								Potential market launch 2024 – partnership with market leader Medix, representing near-term revenue potential through mid-teens royalties and milestone	
Tesomet	HO, PWS									Positioned for partnering following successful phase 2a data (2019)
SAN711	Epilepsy									Positioned for absence seizures following positive phase 1 data (2022). Value-inflection points in 2024/25
SAN903	Fibrotic and inflammatory disorders									Positioned for partnering following successful IND/CTA enabling studies
SAN2219	Epilepsy									Positioned for acute repetitive seizures with multiple expansion opportunities in rare and severe epilepsy
GABA program	Epilepsy									Positioned for rare pediatric epilepsy syndrome with multiple expansion opportunities in rare and severe epilepsy
Kv7 program	Epilepsy									Focal/Generalized Epilepsy Lead optimization
AstronauTx	Alzheimer's									Partnership agreement entitling Saniona to milestone payments of up to USD 177m plus royalties
Boehringer Ingelheim	Schizophrenia									Partnership agreement entitling Saniona to milestone payments of up to EUR 76.5m plus royalties
Cephagenix	Migraine									Joint venture, Saniona owns 33%

Saniona poised for success in epilepsy



Focused epilepsy pipeline addressing indications with significant medical need



Selective ion-channel modulators maximize efficacy and minimize adverse effects



Precision medicines addressing underlying pathology with disease modifying potential



Predictive preclinical models and innovative clinical study design with objective endpoints and on-target biomarkers enhance success rate



Experienced team with deep expertise in CNS and ion-channel drug discovery and development including GABA PAMs and Kv7 activators

Epilepsy – large market driven by new products addressing significant unmet medical need

- >20 approved Anti Seizure Medications (ASM) – mostly generics
- Top 10 branded ASM accounted for 80% of sales in 2022¹
- Top branded products and companies expected to change within 5 years¹
- 30% drug resistant >1.5 million patients in 7 Major Markets
- Paediatric Syndromes, often drug resistant to broad spectrum ASM, have devastating life-long consequences for patients and families
- Recently introduced ASMs demonstrate that market remains interesting for products addressing unmet medical needs
 - For adults with generalized/focal onset seizure: Xcopri/Ontozry (SK BIO) and XEN1101 (Xenon) in phase 3 are expected to reach more than USD 1B and USD 750m respectively in 2028
 - For paediatric Orphan Diseases: Epidiolex (Jazz) and Finteplay (UCB) are expected to reach USD 1.2B and USD 800m respectively in 2028

Global Epilepsy Market



50 million

People affected by epilepsy worldwide²
>9 million people in the US and EU^{3,4}



30%

Resistant to existing therapies⁵



>4%

Annual growth⁶



USD 8 billion market

By 2028⁶

1) Evaluate pharma; 2) World Health Organization; 3) bialepilepsy.com/epilepsy/facts-figures/; 4) Zack MM, Kobau R. National and state estimates of the numbers of adults and children with active epilepsy — United States, 2015. MMWR. 2017;66:821–825. DOI: 10.15585/mmwr.mm6631a1; 5) Kwan et al 2000 New England Journal of Medicine; Chen et al 2018 JAMA Neurology; 6) Evaluate Pharma, estimated growth 2022-2028

Epilepsy has been subject to several recent deals

Investor	Target	Deal	Year	Transaction size	Comment
		Acquisition	2022	USD 1.9 billion	Worldwide rights to fenfluramine (Fintepla®) for the treatment of seizures associated with Dravet syndrome
		Acquisition	2021	USD 7.2 billion	Worldwide rights to cannabidiol (Epidiolex®) for the treatment of seizures associated with Lennox-Gastaut Syndrome, Dravet Syndrome and Tuberous Sclerosis Complex
		Acquisition	2021	USD 960 million	EU rights of cenobamate (Ontozry®) for the treatment of drug-resistant focal-onset seizures in adults
		Collaboration	2017	USD 856 million	Total payments of up to USD 856 million incl. USD 196 million upfront and tiered double-digit Royalties on sales for Soticlestat*

*Soticlestat is a Takeda small molecule in Phase 3 development for Paediatric OD indications – Ovid conducted Phase 2 under a collaboration with Takeda for two orphan diseases (Dravet Syndrome and Lennox-Gastaut)

Subtype selective GABA_A PAMs: maximizing efficacy, minimizing adverse events

GABA_A POSITIVE ALLOSTERIC MODULATORS (PAMs):

- Highly effective anti-epileptics but dose-limited by adverse effects
- Modulates all GABA_A receptors ($\alpha 1$, $\alpha 2$, $\alpha 3$ and $\alpha 5$) non-selectively
- GABA_A $\alpha 1$ pharmacology drives major adverse events: sedation, cognitive impairment, abuse liability and tolerance development (reduced effectiveness over time)
- Saniona assets designed to exert highly differentiated pharmacology, specifically tailored to address the unmet needs of specific indications
- Retaining strong seizure control while avoiding the use-limitations associated with non-selective GABA_A PAMs



Therapeutic effect of "Benzoes"	GABA _A $\alpha 1$	GABA _A $\alpha 2$	GABA _A $\alpha 3$	GABA _A $\alpha 5$
Anti-seizure	++	++	++	
Analgesia		++	++	
Anxiolysis		++	+	
Sedation	++			
Tolerance	++			
Addiction	++	+		
Cognitive impair.	++			+

"Benzoes": Benzodiazepines

PAM: Positive Allosteric Modulator

Mohler H Diversity in neuronal inhibition, Dial. Clin. Neurosci. 2002; Knabl J, Reversal of pathological pain through specific spinal GABA_A receptor subtypes, Nat. Lett. 2008 ; Rudolph U et al., Beyond classical benzodiazepines, novel therapeutic potential of GABA_A receptor subtypes, Nat.Rev. Drug Discov. 2012



Saniona GABA_A PAMs: differentiated pharmacology tailored to address unmet need in specific indications

SAN711:

Precision medicine for absence seizures devoid of liability for attentional impairment and birth defects

SAN2219:

Strong seizure control devoid of GABA_A α1 use limitations for acute repetitive seizures

AN2668:

Strong seizure control with additional antiseizure efficacy to treat severe pediatric syndrome

Therapeutic effect	GABA _A α1	GABA _A α2	GABA _A α3	GABA _A α5
Anti-seizure	++	++	++	
Analgesia		++	++	
Anxiolysis		++	+	
Sedation	++			
Tolerance	++			
Addiction	++	+		
Cog. impair	++			+

CNS adverse effects

Target for SAN711

Therapeutic effect	GABA _A α1	GABA _A α2	GABA _A α3	GABA _A α5
Anti-seizure	++	++	++	
Analgesia		++	++	
Anxiolysis		++	+	
Sedation	++			
Tolerance	++			
Addiction	++	+		
Cog. impair	++			+

Target for SAN2219

Therapeutic effect	GABA _A α1	GABA _A α2	GABA _A α3	GABA _A α5
Anti-seizure	++	++	++	
Analgesia		++	++	
Anxiolysis		++	+	
Sedation	++			
Tolerance	++			
Addiction	++	+		
Cog. impair	++			+

Target for AN2668

PAM: Positive Allosteric Modulator

Mohler H Diversity in neuronal inhibition, Dial. Clin. Neurosci. 2002; Knabl J, Reversal of pathological pain through specific spinal GABA_A receptor subtypes, Nat. Lett. 2008; Rudolph U et al., Beyond classical benzodiazepines, novel therapeutic potential of GABA_A receptor subtypes, Nat.Rev. Drug Discov. 2012



Epilepsy Pipeline

Product Candidate	Indication	Expansion opportunity	Research	LOP/CS	Pre-clinical	Phase 1	Phase 2	Status	
SAN711 GABA α 3 PAM	Absence seizures	Generalized idiopathic epilepsy							<ul style="list-style-type: none"> Positive Phase 1 data reported w/ target engagement imaging biomarker
SAN2219 GABA α 2/3/5 PAM	On demand repetitive seizures	Refractory Focal onset epilepsy						<ul style="list-style-type: none"> Ready for Preclinical Development 	
AN2668 GABA α 1/2/3/5 PAM	Rare pediatric DEE-SWAS syndrome	Rare genetically defined loss of function mutations						<ul style="list-style-type: none"> Ready for Preclinical Development 	
Kv7 program Kv7.2/Kv7.3	Refractory Focal onset epilepsy	Rare genetically defined seizures						<ul style="list-style-type: none"> Lead Optimization / Candidate selection 	

LOP: Lead Optimization Phase

CS: Candidate selection

DEE-SWAS: Developmental Epileptic Encephalopathy with Spike Wave activation during Slow wave sleep

Portfolio of precision medicines for epilepsy indications with significant unmet medical need and potential to be first approved and/or first-in-class therapies

Pipeline asset	SAN711	SAN2219	GABA program	Kv7 program
 Indication	Absence seizures (CAE + JAE)	Acute on demand seizure control (ARS)	Developmental epileptic encephalopathy with Spike Wave activation during sleep (DEE-SWAS)	Treatment refractory focal onset seizures
 Prevalent population	CAE, US*: 47-80K (add: 16-26K) JAE, US*: 60-90K (add: 40-60K)	> 300K***	2.4-7K (US)*	FOS, US**: 1.8M (add: 600K)
 Potential Market position	First-in-class Potential to become first-line based on highly differentiated profile	First-in-class Differentiated profile vs. approved Benzodiazepines	First approved treatment Rare pediatric syndrome with high unmet need	Best-in-class Differentiated profile vs. XEN1101
 Key therapeutic value proposition	Precision pharmacology targeting the root cause of the disease pathophysiology without attentional impairment and embryofetal risk	Acute on demand remedy devoid of benzodiazepine use limitations incl. restrictions on treatment frequency	Precision pharmacology targeting the root cause of the seizure physiology with potential to prevent neurodevelopmental disabilities. Devoid of high-dose benzodiazepine- and steroid use limitations	Precision pharmacology reestablishing neuronal inhibition with limited CNS adverse effects, urinary retention problems and retinal abnormalities
 Mechanism	GABA _A α3 PAM targeting SWDs to prevent absence seizures	GABA _A α2/α3/α5 PAM reestablishing neuronal inhibition to arrest cluster seizures	GABA _A α2/α3/α5 PAM targeting SWDs and reestablishing neuronal inhibition in relevant brain circuits	Kv7.2/Kv7.3 activator selectively dampening neuronal hyperexcitability in relevant circuits

Add: Addressable patients; ARS: Acute repetitive seizures; CAE: childhood absence epilepsy; JAE: juvenile absence epilepsy; DEE: Developmental epileptic encephalopathy; FOS: Focal onset seizures; PAM: positive allosteric modulator; SWDs: Spike-Wave-Discharges
 *Saniona sponsored Market analysis (Back Bay Life Science Advisors lead indication report aug-oct 2020); **CDC statistics for 2015: Epilepsy Data and Statistics | CDC and assuming 30% difficult to treat; ***Mesraoua et al J. Drug Assess, 2021,

Potential first-in-class precision medicine for treatment of absence seizures

SAN711

- **ABSENCE SEIZURES** – short episodes of impairment of consciousness caused by aberrant Spike-Wave-Discharges
- First line therapy impairs cognition and carries risk for women of childbearing potential
- Characteristics of Absence seizures¹
 - Cause short period of “blinking out”/staring into space
 - Person suddenly stops all activity
 - Eyes may turn upwards and eyelids flutter
 - Seizures usually last <10 seconds
 - Majority of absence seizures begin during childhood, most commonly from age 4 – 14



Up to 10%
Of all childhood epilepsy²



20%
Are drug resistant²



40%
Continue to have seizures into adulthood²



33%
Have cognitive impairment (attention deficits)²

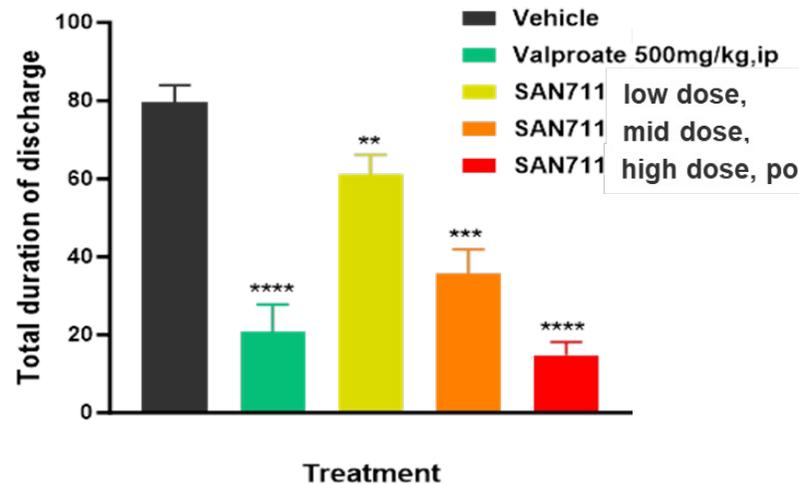
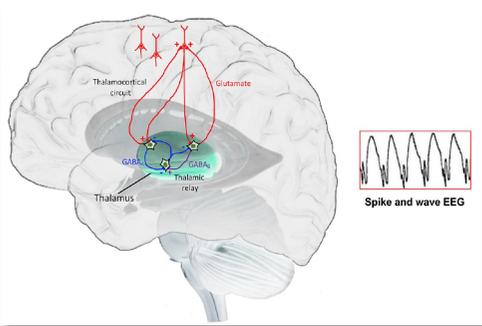
1) epilepsy.com/what-is-epilepsy/seizure-types/absence-seizures; 2) Trinka E et al., Absences in adult seizure disorders. Acta Neurol Scand 2005, Physiol Rev. vol 103, 2023; Glauser T.A et al., Ethosuximide valproate and lamotrigine in childhood absence epilepsy New Engl. J. Med. 2010

Precision medicine by selectively targeting disease pathophysiology

Strong effects in a highly predictable rodent model for absence seizures

SAN711

- Robust effects obtained in two independent studies (academia and CRO)
- SAN711 precision pharmacology prevents absence seizures by abolishing SWDs in specific brain networks
- No detrimental effects on cognition is anticipated
- Specific contribution of GABA_A α3 in SWD prevention established^{1,2}



n = 11 per condition / #**/**/**** p < 0.05/0.01/0.001 as compared to vehicle (two way RM ANOVA, post hoc Fishers test)
Data averaged between 70 and 190 min after administration and normalized for baseline values.

Therapeutic effect	GABA _A α1	GABA _A α2	GABA _A α3	GABA _A α5
Anti-seizure	++	++	++	
Analgesia		++	++	
Anxiolysis		++	+	
Sedation	++			
Tolerance	++			
Addiction	++	+		
Cog. impair	++			+

Target for SAN711

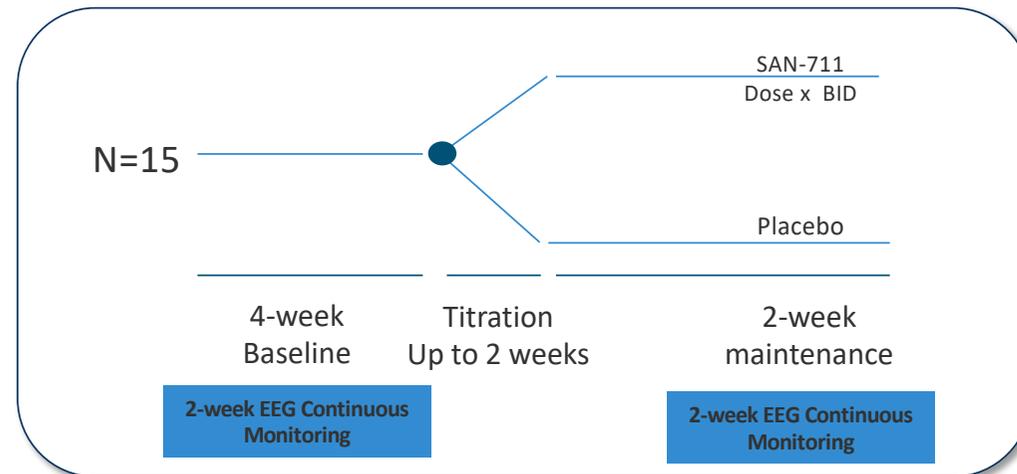
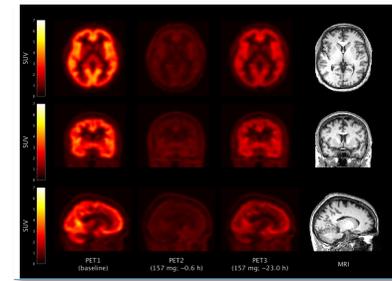


¹Duveau et al., CNS neurosci. Ther. 2019
²<https://ir.avenuetx.com/news-events/press-releases/detail/73/avenue-therapeutics-announces-high-potency-and-full>

Innovative trial design for Proof of Concept Objective Endpoint with Dose Selected based on Target Engagement Biomarker

SAN711

- PoC– Single Country (BE) - multi-centre (Brussels, Leuven, Gent)
 - double-blind, placebo controlled, parallel-group study to assess Effect on EEG and Absence Seizures using a validated device¹
- N=15 patients randomized 2:1
 - Active dose selected based on available PK-RO data (PET Imaging Target Engagement)
 - ~2-week titration + 2-week maintenance period



Saniona Kv7 activators: Unique subtype selective Kv7.2-7.3 activators with potential to be devoid of dose-limiting CNS adverse effects and blue discolorations

AN10255

Kv7 ACTIVATORS:

- Non-selective activators proven effective in treatment refractory focal onset epilepsy (Retigabine, Trobalt®/Ezogabine®)
- Withdrawn in 2017: blue discoloring of skin, retinal abnormalities caused by unstable chemistry, urinary retention, CNS adverse effects
- Saniona’s subtype selective assets shows unique differentiated profiles with strong antiseizure control maintained while adverse effect profiles superior to non-selective comparators
- New chemistry avoiding unstable metabolite (blue discolorations)



	Kv7.1	Kv7.2	Kv7.3	Kv7.4	Kv7.5
Regulator of neuronal activity in the brain		++	++		+
Regulator of electrical activity in the heart	++				
Regulator of bladder smooth muscle cell activity				++	+

AE: adverse effects, Brickel et al., Epilep. Behav. 2020; Ioannou P et al., Brain Behav. 2022, Kwan P et al., Epilepsia 2010, Laxer KD et al., Epilepsia and Behavior 2014, <https://www.neurologylive.com/view/anticonvulsant-potiga-discontinued-june-2017>



Unique selective activator of Kv7.2-7.3 subtypes

Differentiated pharmacology with strong seizure control and superior adverse effect profile

AN10255

- **DRUG REFRACTORY FOCAL ONSET EPILEPSY** evades standard antiseizure medication
- 30 % unable to achieve seizure freedom
- Severely increases the disease burden:
 - increased premature mortality, increased morbidity, lower quality of life than controlled epilepsy
- AN10255 unique selectivity profile retaining strong anti-seizure activity while avoiding CNS- urinary retention adverse effects and adverse events caused by metabolic instability (retinal- and skin discoloration)

Rodent model	Seizure type	Activity
6 Hz	Focal seizures	✓
MEST test	Generalized Tonic Clonic seizures	✓
Asset	Fold difference between effect and CNS AEs*	
XEN1101	approx. 2-4	
AN10255	Approx. 25	

*Fold difference in free plasma concentration between efficacious doses and doses causing CNS adverse effects

	Kv7.1	Kv7.2	Kv7.3	Kv7.4	Kv7.5
Regulator of neuronal activity in the brain		++	++		+
Regulator of electrical activity in the heart	++				
Regulator of bladder smooth muscle cell activity				++	+

Target for AN10255

Urinary retention

CNS AEs

CNS: Central Nervous System; AE: Adverse Effect; Ioannou P et al., Brain Behav. 2022, Kwan P et al., Epilepsia 2010, Laxer KD et al., Epilepsia and Behavior 2014, <https://www.neurologylive.com/view/anticonvulsant-potiga-discontinued-june-2017>

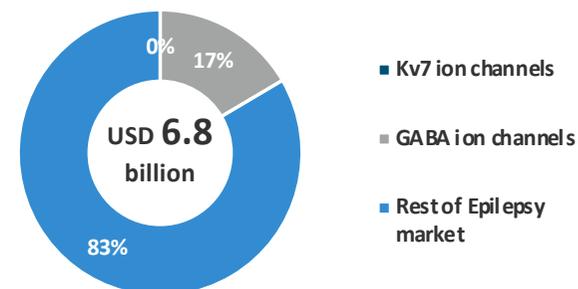
Advancing current epilepsy pipeline – potential to close valuation gap to peers

	Market cap (USDm) ¹	Comment
Cerevel Therapeutics	4.049	Dopamine agonist for Parkinson's (Phase 3) and GABA 2/3 PAM (Darigabat) for epilepsy (Phase 2)
Biohaven	2.149	Glutamate program for ataxia and OCD (Phase 3) and Kv7 program for epilepsy and bipolar disorder (Phase 1)
Xenon Pharmaceuticals	1.980	Kv7 program (X1101) for focal onset seizures (Phase 3)
Sage Therapeutics	1.061	GABA and NMDA platform for various indications and clinical stages. Old GABA PAM (steroid) product recently approved for postpartum depression
Marinus Pharmaceuticals	357	Ganaxolone, old GABA PAM (steroid), for various epilepsy indications incl. CDKL5 disorder (approved), Status Epilepticus (Phase 3), Tuberous Sclerosis (Phase 3)
Ovid Therapeutics	231	Partner (Takeda) in Phase 3 for epilepsy syndrome Internal programs in Phase 1 or pre-clinical
Praxis Precision Medicines	129	Na blocker and type-T calcium channel blocker in Phase 1/2 for epilepsy and essential tremors
Saniona	31	Three GABA PAM programs (SAN711 (phase 2 ready), SAN2219 (preclinical), GABA program (preclinical) and a Kv7 program (LOP/CS)

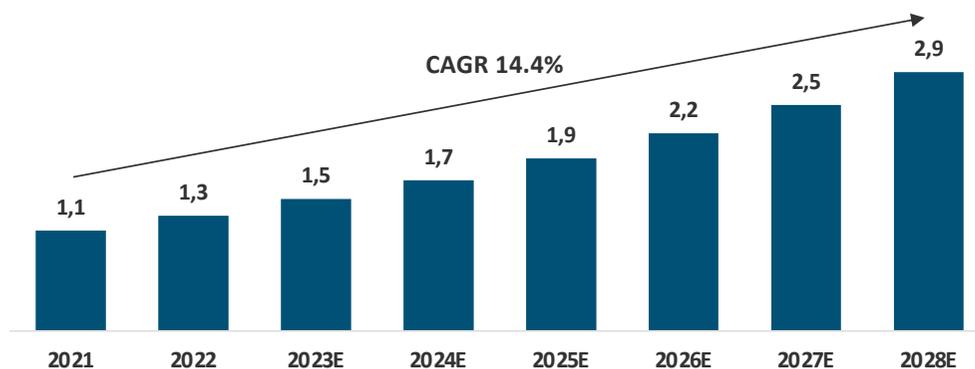
GABA and Kv7 ion channel compounds expected to outgrow the Epilepsy market

- Saniona’s GABA-program and Kv7-program have potential to provide significant value
- Development of GABA and Kv7-program prioritized by Saniona
- Current Kv7-programs highly valued
 - Xenon’s Phase 3 Kv7-program XEN1101 – NPV of USD 2 billion¹
 - Biohaven’s Phase 1 Kv7-program – NPV of USD 795 million²

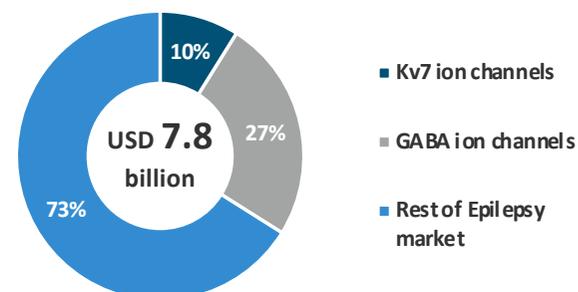
Epilepsy market 2021



GABA & Kv7 ion channel compounds combined market size³ (USD billion)



Epilepsy market 2028



1) Evaluate Pharma, Company | Xenon Pharmaceuticals | Report, 2023-10-17; 2) Evaluate Pharma, Company | Biohaven | Report, 2023-10-17; 3) Evaluate Pharma, Market Value by MoA, 2023-10-17

Eating disorders candidates – targeting market launch and partnering

- **Tesofensine** – targeting market launch 2024

- Q1 2023 Mexican regulatory authority expressed favorable opinion¹ for treatment of obesity
- Partnership – market leader Medix 
 - Near-term revenue potential in 2024
- Initially targeting obesity market in Mexico with potential to expand into other territories

Mexican obesity market

- 75% of Mexican people are obese or overweight²
 - Huge unmet need
- USD 190m by 2023³
- 16% CAGR³

- **Tesomet** – positioned for partnering following successful phase 2a data (2019)
- Orphan designated drug targeting two rare diseases
 - Hypothalamic obesity (HO)
 - Impacts up to 65,000 people in the US and EU^{4,5,6}
 - Prader-Willi syndrome (PWS)
 - Impacts up to 84,000 people in the US and EU^{7,8}

1) "Saniona's partner Medix receives favorable opinion for tesofensine for the treatment of obesity and weight management in Mexico"; 2) 2018 data on Mexico by ENSANUT (the National Survey on Health and Nutrition); 3) Medix estimates; 4) Bunin et al. The descriptive epidemiology of craniopharyngioma. J Neurosurg, 89 547-551 (1998). doi:10.3171/jns.1998.89.4.0547; 5) Zacharia et al. Incidence, treatment and survival of patients with craniopharyngioma in the surveillance, epidemiology and end results program. Neuro-Oncology, 14 1070-1078. (2012). doi:10.1093/neuonc/nos142; 6) NIH GARD: rare diseases.info.nih.gov/diseases/6463/hypothalamic-obesity; 7) Manzardo et al. Survival trends from the Prader-Willi Syndrome Association (USA) 40-year mortality survey, Genet Med 20, 24–30 (2018) doi:10.1038/gim.2017.92; 8) National organization of Rare Diseases: rare diseases.org/rare-diseases/prader-willi-syndrome/

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saniona™

Thank You

