# Saniona™

Clinical-stage biopharmaceutical company focused on neurological and psychiatric diseases

Leader in ion channel drug discovery and development

SANIONA PRESENTATION, Q1 2025

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## Investment highlights

- **Broad pipeline:** Advancing three internal programs to Phase 2
- Several partnerships: Two strategic clinical collaborations and three research partnerships with leading industry players, supporting pipeline development and de-risking R&D efforts
- **Potential obesity product approval in Mexico:** A key milestone that will establish a new revenue stream and serve as a springboard for expansion into additional Latin American and potentially global markets
- **Ion Channel Drug Discovery platform:** A validated CNS-focused platform, supported by strong partnerships and significant revenue generation, with research fully funded through existing collaborations.
- Strong financial position: Current cash reserves and anticipated milestone payments provide runway to advance three key assets to Phase 2 clinical trials over the next three years
- Near-term revenue stream opportunities: 1) a \$10M milestone payment from Acadia, 2) potential royalties from Medix, 3) secured research funding with potential milestones under research collaborations, and 4) potential new partnerships
- **Back to partnership business model:** A proven approach that has successfully created a robust pipeline and secured high-value deals, enabling sustainable, self-financed growth over time.



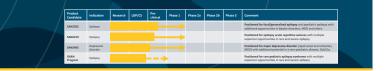
## Saniona Pipeline

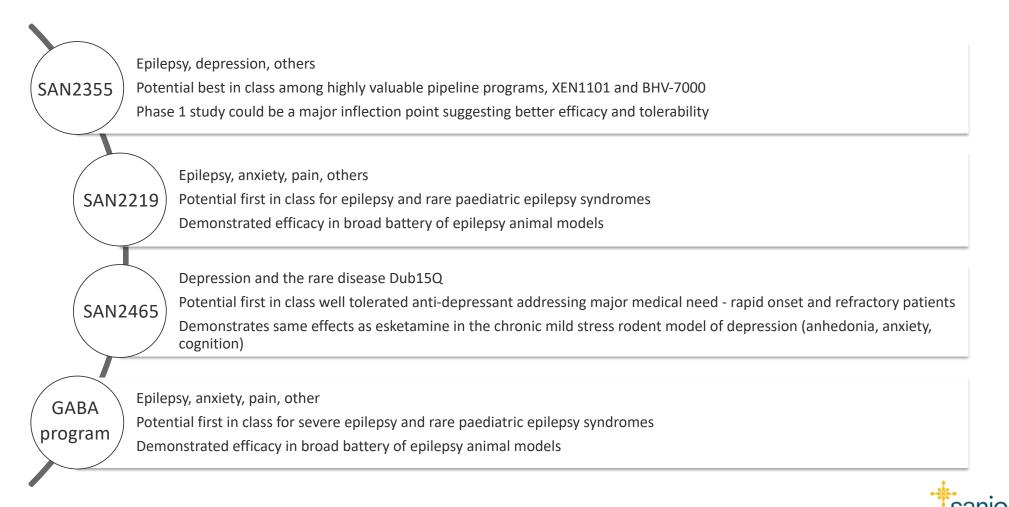
Product Candidate	Indication	Research	LOP/CS	Pre- clinical	Phase 1	Phase 2a	Phase 2b	Phase 3	Comment	
SAN2355	Epilepsy								<b>Positioned for focal/generalized epilepsy</b> and paediatric epilepsy with additional opportunities in bipolar disorders, MDD and others	
SAN2219	Epilepsy								Positioned for epilepsy acute repetitive seizures with multiple expansion opportunities in rare and severe epilepsy	
SAN2465	Depressive disorder								<b>Positioned for major depressive disorder</b> (rapid onset and refractory MDD) with additional potential in a rare paediatric disease, Dub15q	
GABA Program	Epilepsy								Positioned for rare pediatric epilepsy syndrome with multiple expansion opportunities in rare and severe epilepsy	
Tesofensine Medix	Obesity								Under regulatory review – partnership with Mexican market leader Medix, near-term revenue potential through double digit royalties	
Tesomet	HO, PWS								Positioned for partnering following successful phase 2a data (2019)	
ACP-711 Acadia	Essential tremor								Partnership entitling Saniona to <b>milestone payments of up to USD</b> 582m plus royalties	
SAN903	IBD, Fibrotic / inflammatory								Positioned for partnering following successful IND/CTA enabling studies	
AstronauTx Program	Alzheimer's		-						Partnership entitling Saniona to <b>milestone payments of up to USD</b> 177m plus royalties	
Boehringer Program	Schizophrenia								Partnership entitling Saniona to milestone payments of up to EUR 76.5m plus royalties	
Cephagenix Program	Migraine	-							Joint venture, Saniona owned 33% prior to seed financing in Dec 2024	

ship - In-house development



#### Internal Pipeline





#### Recent developments and status

#### Major Millstones since H2 2022

- Three new deals
  - \$610 million Phase 1 deal with Acadia for essential tremor
  - Research collaborations with AstronauTx for Alzheimer's
  - \$9 million VC financing of Cephagenix for migraine
- Three new promising clinical candidates to our pipeline
  - SAN2219 for epilepsy
  - SAN2355 for epilepsy
  - SAN2465 for depression
- Development milestones
  - Favorable opinion for MAA on tesofensine for obesity in Mexico
  - Readouts from two successful clinical studies on SAN711 (ACP-711)
  - Preclinical development of SAN2355 Part 1 completed

#### Status March 2025

- Saniona AB share March 18, 2025
  - Share price: SEK 7.07 per share; Market Cap: 796 MSEK
- Strong Financials Position at year-end 2024
  - Net profit: 189 MSEK; Cash: 303 MSEK; Balance: 340 MSEK
  - About 500 MSEK available including TO4 and Acadia milestone
- TO4 due on April 1, 2025
  - 21.5 million TO4s (one TO4 -> right to subscribe one share)
  - Exercise price: SEK 4.88 -> up to SEK 115 million
  - Subscription period ends on April 1, 2025
  - Lean operation with 22 employees
    - 5 in general and admirative activities
    - 17 in research and development (fully funded)



## Strategy for the next 3 years

#### • Build Value in Pipeline to Enable Strategic Opportunities

- Invest proceeds from the Acadia deal into three high-potential assets to advance them to Phase 2 clinical trials
- Pursue significant license agreements or exit opportunities in 2-3 years
- Retain assets to conduct Phase 2 studies, further enhancing their value
- Maximize Value from Research Platform and Innovation
  - Drive existing research collaborations with potential milestone payments, royalties, and/or equity stakes
  - Ensure continued financing through existing or and/new collaborations
- Increase Reputation and Knowledge in Investor Community
  - Increase visibility in the retail market as the company transitions out of turnaround stealth mode
  - Expand visibility among banks, analysts, and institutional investors through initiatives such as non-deal roadshows
- Diversify Funding Sources to Reduce Stock Market Dependency
  - Secure mid-term funding for Phase 2 clinical trials in 2027 through new licensing agreements
  - Potential royalty income from tesofensine for obesity



# Successful partnership history

	ACADIA AstronauTx Boehringer Ingelheim Cephagenix Boehringer Ingelheim	License agreement - Essential Tremor R&D collaboration/license - Alzheimer's R&D collaboration/license - Schizophrenia Joint venture'- Migraine	300 23 46	<ul> <li>\$582 million milestones + royalties</li> <li>\$177 million milestones + royalties</li> <li>€76 million milestones + royalties</li> </ul>
	Boehringer Ingelheim	R&D collaboration/license - Schizophrenia		
	Cephagenix	· ·	46	£76 million milestones + royalties
		Joint venture´- Migraine		ero minori miestories + royanies
	Boehringer		10	Equity, milestones, warrants
	Nillingeineim	R&D collaboration/license - Schizophrenia	111	Regained program
	PROUMAGEN	R&D collaboration/license – Neurological	17	Regained program
	SCANDION ONCOLOGY	Spinout public listed - cancer	126	(Equity capitalised)
	medix	Development/regional license - obesity	20	Milestones + mid-teens royalties
	THE MICHAEL & FOX FOUNDATION FOR PARENEOUN RESEARCH	Grant – Parkinson's disease	2	
	Initiator Pharma	Spinout public listed - Erectile defunction		Royalties (equity distributed to shareholders)
	Pfizer	R&D collaboration/license	16	Regained program
CA Ther	DENT UNOVARTIS	Spinout acquired by Novartis – Ataxia	61	Earnouts + royalties (equity capitalised)
2012	Janssen 🕇	R&D collaboration/license – Alzheimer's	17	Regained program
		Other	5	(Other grants and undisclosed)
		Total	755	



## Saniona's Partnerships Business Model and Track Record

- Saniona has followed the partnership business model from 2012–2020 and from mid-2022 to today
- Achievements during partnership business periods:
  - SEK 755 million in income and a profit of at least SEK 117 million
  - Secured valuable collaborations with near-term milestones and upside
  - Financed six internal clinical studies
  - Build pipeline from scratch (apart from tesofensine)
- Track record demonstrates the strength of the model and Saniona's ability to commercialize its assets
- Profit calculations
  - Shifted to go-to-market strategy with Tesomet in 2020 to mid-2022:
    - Resulted in SEK 775 million operating loss
    - Near bankruptcy after failing to list in the US
  - In 2022 we closed US office, replaced management, and returned to partnership business model
  - Saniona's accumulated deficit at year-end 2024: SEK 666 million
    - Adjusted for go-to-market loss  $\rightarrow$  SEK 117 million profit from partnerships



## Saniona commercializes its assets in all stages of drug discovery and development



Target validation, Lead op., Candidate selection

#### **Research Collaboration**

Saniona agreements are typical world-wide rights

- Option Agreement
   AstronauTx
- License Agreement
- Boehringer Ingelheim
- Spinouts / Joint ventures Cephagenix



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#### Strategic Development Collaborations

- World-wide License Agreement Acadia (Phase 1)
- Regional License Agreements
- Medix (Mexico and Argentina, Ph 3, now under regulatory approval)



Regulatory, CMC, Branding

#### Commercialisation Collaborations

• **Regional deals** for tesofensine in new territories following approval in Mexico



### Research collaboration create value – even if they don't succeed

#### **Key Pros:**

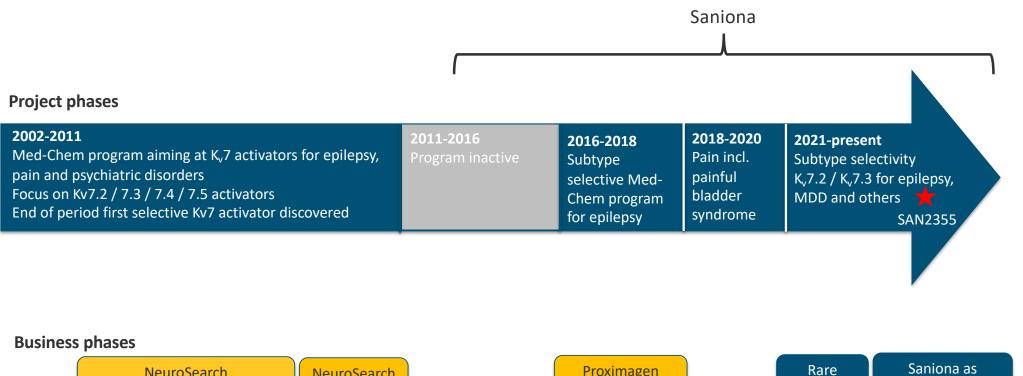
- The return-risk ratio is extremely attractive if successful
- Saniona has little to no financial risk since our costs are reimbursed on fully loaded basis
- Significant upside potential:
  - AstronauTx: \$177 million plus royalties
  - Boehringer Ingelheim: \$74 million plus royalties
  - Cephagenix: Ownership, success-based warrants, commercial milestones, and the option to invest in future rounds (risk-sharing)

#### **Key Cons:**

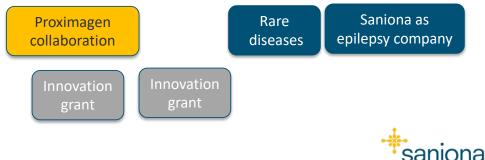
- Most research collaborations don't succeed, but:
- Many of Saniona's terminated collaborations ended for strategic reasons, giving us the chance to:
  - Out-license the program again, or
  - Continue developing the asset internally
- Our share price often drops in these situations but this could be our biggest opportunity
  - We've resold some assets several times at higher prices thanks to the value created in past collaborations
  - Some of our most promising drug candidates came from collaborations with major pharma



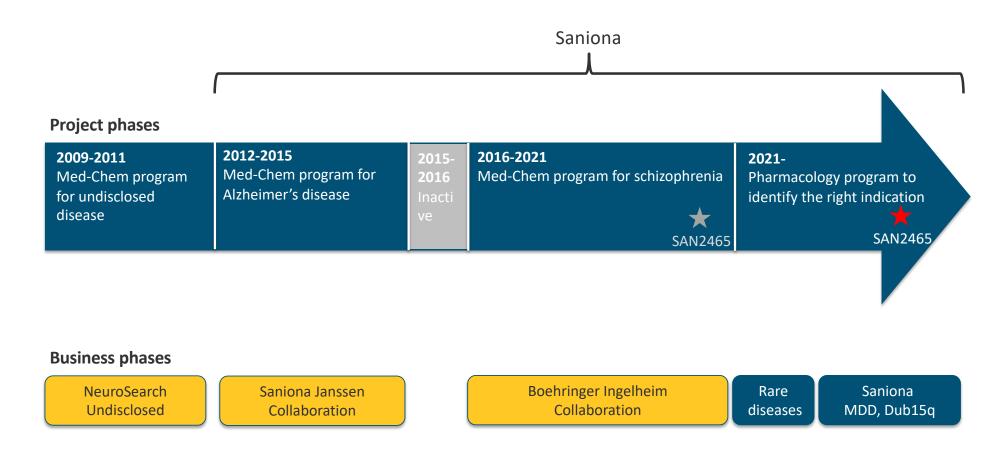
## Saniona K<sub>v</sub>7 Program History - now positioned for epilepsy







## Saniona GABA<sub>A</sub> $\alpha$ 5 NAM Program History - now positioned for MDD





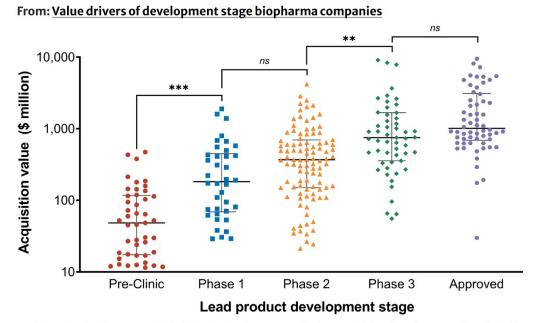
## Development collaborations create more value than research collaborations

- It takes 5-10 years to reach a high-quality small molecule drug candidate from scratch
- The potential deal value increases significantly once a program enters clinical development (Phase 1, 2, and 3)
- Development is more expensive than research, but the potential rewards are much greater
- Developing drugs creates more value than early-stage research
- Saniona is in a strong position:
  - Four high-quality candidates with strong and long patent protection
  - Funding secured to advance three of them to the next major milestone
  - Preparing for non-dilutive funding by potentially selling one program after the next major milestone (e.g., Phase 1) to advance others further



## Acquisition value of 311 transaction of US and EU BioPharma from 2005-2020

Source: Value drivers of development stage biopharma companies, the European Journal of Health Economics



Acquisition value of Biopharma companies by lead product development stage. All values were inflation adjusted to 2020. *p* values calculated based ANOVA with Turkey's multiple comparison test: \*\*p < 0.01, \*\*\*p < 0.001, ns not significant

#### Comment

- 4x increase in value from preclinical to phase 1, and 2x for each following stage
- Wide variation in value depending on indication, risk, development costs, market size, competition etc.
- "Preclinical" is often loosely defined and may not include CTA/IND-enabling work in all deals
- The value of Phase 2 is higher than Phase 1 but not significantly—likely due to how the phases are defined:
  - Difference between Phase 2a and 2b
  - Difference between Phase 1b and 2a
  - Strong biomarkers in Phase 1 can reduce a lot of perceived risk

Lead asset	Pre-clinical	Phase 1	Phase 2	Phase 3	Approved
Mean deal value, \$ million	88	354	683	1,761	2,469
Mean upfront, percent	51%	43%	72%	80%	95%



## About Saniona-Acadia Phase 1 collaboration

#### • WW license agreement for ACP-711 (SAN711) - currently in Phase 1

- First indication: Essential tremor
  - Affects 7 million patients in the U.S.<sup>1</sup>
  - No innovation in over 30 years despite medical need
  - Ulixacaltamide (T-type calcium channel blocker) is the only product in development, currently in Phase 3 with Praxis
  - Analyst estimates: Launch 2026, peak sales \$1.7 billion, eNPV of \$1.9 billion<sup>2</sup>
- Other potential indications: Additional tremors, absence seizures, sleep disorders, neuropathic pain and more...

Financials	US\$ million
Upfront payment	28
Initiation of Phase 2 clinical studies (expected 2026)	10
Reimbursement of Phase 1 and Phase 2 preparation	
Other development and regulatory milestones	137
Commercial milestones	435
Total deal value	610
Royalties on net sales	Mid-single to low-double digit



ACADIA

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#### About the Saniona-Medix Phase 3 collaboration



Medix responsible for clinical development, regulatory approval and commercialization in Mexico and Argentina.

Medix, right to market tesofensine in Mexico and Argentina. Saniona entitled to milestone payments and royalties on net sales in Mexico and Argentina.

Saniona responsible for manufacturing API whereas Medix may manufacture drug product for Mexico and Argentina. Saniona has commercial rights in rest of world including data developed by Medix.



Potential approval of tesofensine in Mexico in 2025

Medix conducted successful Phase III obesity study in Mexico and filed for registration of tesofensine in Mexico in 2019.

Medix received favorable opinion from COFEPRIS' technical committee on new molecules on tesofensine for treatment obesity in 2023, awaiting final decision for potential approval in Mexico in 2025.

Medix to conduct long-term (1-year) Phase IV study following approval and launch of tesofensine in Mexico.



## Stepwise global market launch in obesity following approval in Mexico



Launch of tesofensine in Mexico together with partner and market leader Medix



#### Mexican obesity market

- 47% adults with obesity projected 2035<sup>2</sup>
- **2.1%** annual increase in adult obesity 2020-2035<sup>2</sup>
- USD 150m by 2024<sup>3</sup>
- High CAGR following Covid temporally mitigated by withdrawal of major product<sup>4</sup>



Continue commercial expansion alone or together with Medix – targeting Brazil, Argentina, Colombia, Peru, and Chile – small or no additional studies may be required

Further expansion into South Korea, minor bridging studies may be required



Explore pathway for U.S, and other major markets by building business case for implementation together with partner

End of P2 meeting with the FDA and scientific advice with EMA to discuss strategy for approval US/EU

Conduct Phase III studies in collaborations with partner

Following completion of the required Phase III studies - US/EU and Japan, China



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## Key 2025 Milestones

$\bigotimes$	45 <b>3</b> 1	Saniona's joint venture, Cephagenix, raise up to €9 million seed financing	Q1 2025
Ø		Top-line results from ACP-SAM711 Phase 1 biomarker study	Q1 2025
Ø	<b>P</b>	Initiation of 2 <sup>nd</sup> part of preclinical development for SAN2355 epilepsy asset	Q1 2025
		Initiation of preclinical development for SAN2219 epilepsy asset	Q1 2025
		Initiation of preclinical development for SAN2465 MDD asset	Q1 2025
	€	Result from TO4 financing	Q2 2025
	ø	Potential regulatory approval of tesofensine for obesity in Mexico	Q2 2025
	Ē.	Potential Candidate Selection Milestone on AstronauTx or Boehringer Ingelheim	H2 2025
	<b>A</b>	Completion of CMC tox batch for SAN2219 epilepsy asset (Preclinical Part 1)	H2 2025
	<b>A</b>	Completion of CMC tox batch for SAN2465 MDD asset (Preclinical Part 1)	H2 2025
		Finalize IND/CTA package for SAN2355 epilepsy asset for Phase 1 clinical trial	H2 2025
	45 <b>51</b>	Potential new license and collaboration agreements	2025





## Saniona's journey on the Stockholm Stock Exchange



saniona

Market Cap (MSEK)

Saniona's accumulated deficit was SEK 666 million at year-end 2024. But the operating loss was SEK 775 million under the go-tomarket strategy suggesting a profit of SEK 117 million during the periods where Saniona followed the partnership business model.

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