

AN EMERGING GLOBAL PHARMACEUTICAL COMPANY

Revolutionizing the Delivery of Rescue Treatments

Powered by the Innovative ZENEO® Needle-Free
Auto-Injector Technology Platform



CROSSJECT

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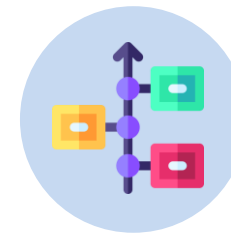
CROSSJECT - AN EMERGING GLOBAL PHARMACEUTICAL COMPANY



Headquartered in Dijon (*France*)
110 employees in France and the U.S.



Unique foundational technology
and validated ZENEO® needle-free
auto-injector



3 focus Rx products with
targeted regulatory
submissions, starting with
EUA in early 2025



Landmark R&D and supply
collaboration with BARDA* –
up to \$155M



Growing presence in North America
to accelerate commercialization of
ZEPIZURE®** in epilepsy markets,
starting with EUA

HIGHLY EXPERIENCED SENIOR LEADERSHIP TEAM



Patrick ALEXANDRE
Founder & CEO

Chairman of the executive Board
35 years experience
Arcelor, Fournier labs.
Founder in 2001



Isabelle LIEBSCHUTZ
Quality & Regulatory Director

Member of the executive Board
26 years experience
Fournier labs, Solvay, Plasto Santé
Joined in 2013



Tony TIPTON
COO - USA

Head of USA
27 years experience
Xequel Bio, Santen, Eyevance,
Sunovion, Galderma, Sanofi-Dermik
Joined in July 2024



Olivier LACOMBE
Pharma Development Director

18 years experience
Fournier labs, Abbott, Solvay, Inventiva
Joined in 2021



Marianne SVENSSON
Administrative & Finance Director

24 years experience
Savoie, DS Smith
Joined in 2022



Didier MORIN
Industrial Director

28 years experience
IDS, Axess Vision
Joined in 2023

ZENEO® - Technology Features

**One Quick-Click
Full-Dose Delivery**



User-Intuitive



Needle-free Injection



Versatility

drug, depth, viscosity...



Strong IP



ZENEO® - Development History



20+ years of R&D driven by a Subject Matter Experts multidisciplinary team



10,000+ Device Tests



12 Clinical Trials, 500+ subjects



~ €180M investment

Validated easy administration via successful Human Factors studies

Robust testing in diverse and untrained populations in stressful situations
- Adults, Children, BARDA* -



1200+ participants for all Human Factors studies



Use success rate as high as **99.6%****



Intervention and **full-dosage administration < 1 minute**

Proven and recognized ease of use by multiple Awards



ADAPTABILITY OF ZENEO[®] PLATFORM TO A LARGE RANGE OF MOLECULE INDICATIONS



Flexible

Adjustable penetration pressure, drug delivery, and allows for variation in molecule size and vehicle viscosity



Versatile

Leverages the same components and manufacturing processes to ensuring cost efficiencies



Streamlined

Eligible for regulatory programs with shorter approval timelines and less clinical requirements
→ **505(b)(2)**



Reliable

Meets FDA regulatory compliance standards
→ **99,999%**

PRODUCT CANDIDATES PORTFOLIO



MARKET OPPORTUNITY – SIGNIFICANT INITIAL TARGET MARKETS

ZENEO® : An intuitive, easy and safe device, designed for emergency situations outside of hospital

Epileptic Seizures

- **Status Epilepticus, as a first indication, is categorized as a Rare Disease***
- Global Epilepsy prevalence ~65m ⁽¹⁾
- Estimated up to ~ 40% of epilepsy patients are refractory to chronic treatments = uncontrolled seizure ⁽²⁾

Global Epilepsy Rx Market ~\$10B ⁽³⁾
US Epilepsy Rx Market ~\$4B ⁽⁴⁾
Global Status Epilepticus Rx Market ~\$1.2B ⁽⁵⁾

Anaphylaxis (ANA)

- Estimated 1 in 20 Americans experience the life-threatening symptoms of ANA ⁽⁶⁾
- US Emergency Department visits for ANA for children increased from 11.9/100,000 to 35.2/100,000 over the past 10 yrs.
- Global prevalence is estimated to be 46 cases per 100K people

Global ANA Rx Market ~\$6B ⁽⁷⁾
US - 5.2m 2-pkg.auto-injectors sold annually ⁽⁸⁾

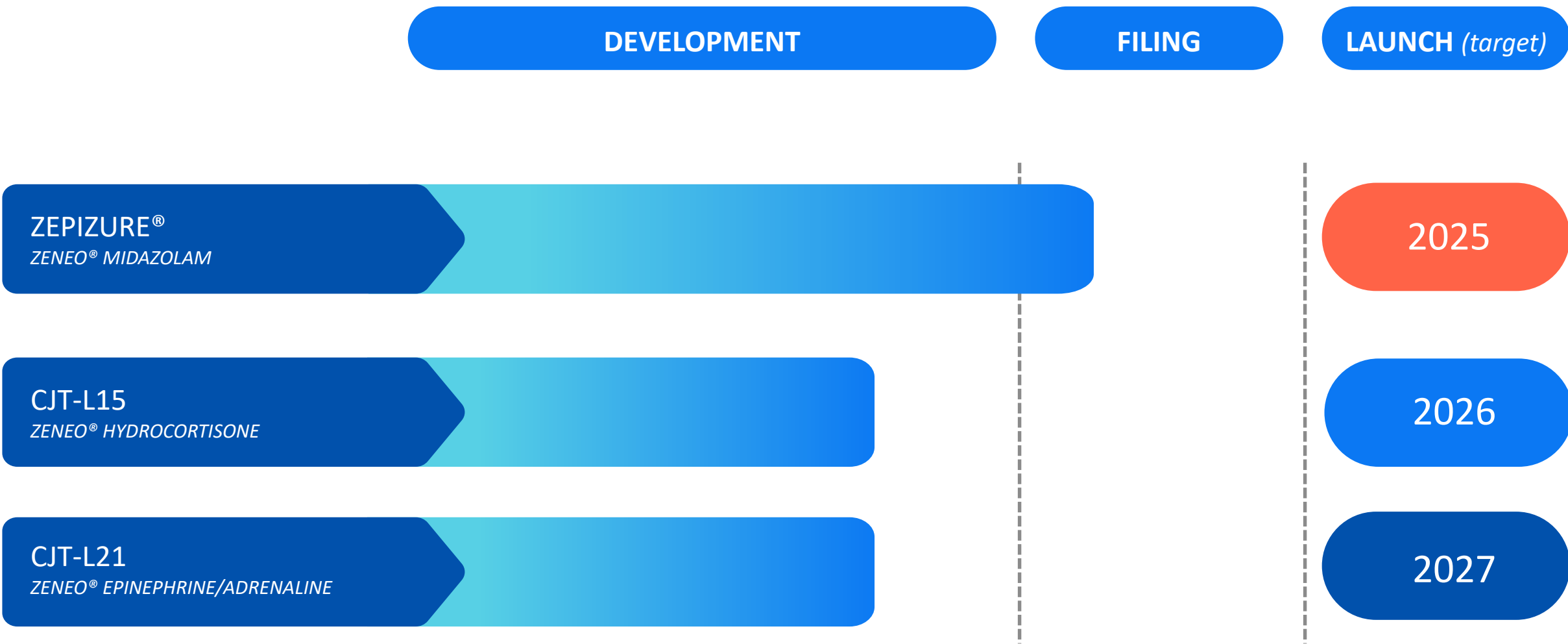
Acute Adrenal Crisis (AAC)

- **Rare Disease*** with an 0.5% mortality rate, up for population with adrenal insufficiency to 6% ⁽⁹⁾
- US and Europe prevalence 5/10,000, US prevalence 100,000+ ⁽¹⁰⁾
- AAC's severe life-threatening symptoms require immediate treatment - SOC is Hydrocortisone IM injection

US AAC Rx Market ~\$85M+

* CROSSJECT received U.S. FDA Orphan Designation for Zepizure® (Midazolam) for treatment of Status Epilepticus on January 30, 2018, but cannot receive potential Orphan Drug Exclusivity (ODE) unless Zepizure® is approved by FDA under a New Drug Application. An Emergency Use Authorization (EUA) will not qualify Zepizure® for ODE. CROSSJECT has not requested nor received FDA or EU Orphan Drug Designation for hydrocortisone for AAC."

ACTIVE PIPELINE SUMMARY



FOCUS ON ZEPIZURE® – A NEW PARADIGM FOR RESCUE INJECTIONS



EPILEPSY SEIZURE RESCUE

PREVALENCE

- Global prevalence ~65M ⁽¹⁾
- US - Up to ~40% of epilepsy patients still experience uncontrolled seizures due to being refractory to their chronic treatments ⁽²⁾

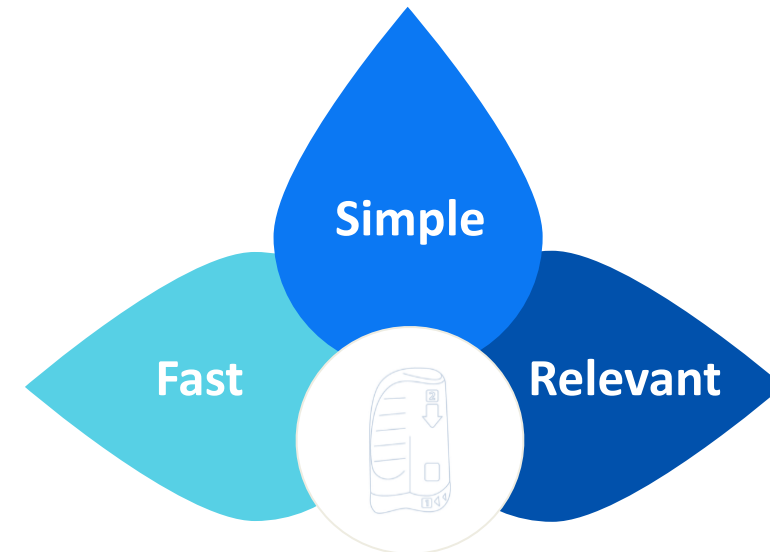
UNMET NEED

- In US, 1.9 million seizure related EMS calls annually (3% to 5% of EMS* calls) ⁽³⁾
- Status Epilepticus episodes increases mortality to 22% over 30 days, 31% >10 years ⁽⁴⁾
- More than 5000 US deaths per year related to epilepsy ⁽⁵⁾

CURRENT & SOC

- IM syringe & needle injections of Midazolam are Standard of Care (SOC) for seizure rescue for hospitals and EMS services
- Nayzilam® and Valtoco® nasal sprays are considered the preferred seizure rescue SOC
- No current FDA approved seizure rescue medications are indicated for Status Epilepticus

Simple 2-step administration
First-time user success rate as high as 99.6% in Company human factors testing, no formal training



Unpacking & Administration requires <60 secs

Needle-free "Quick-Click" injection takes 1/10th of a second for full dose...traditional needle/syringe are typically 3-10 secs injections

PK Bioequivalence vs 30mm IM injection, Midazolam



Dosage variability reduced vs transmucosal delivery

Bioequivalence with ZEPIZURE® bare skin vs through clothing



Mission: Execute a 3-stage Strategic Commercial Plan to drive sales and revenue growth

  I Deliver BARDA's orders as Part of \$155M contract* (Strategic National Stockpile Program)



  II US commercial launch positioning ZEPIZURE® as the new treatment of choice and best-in-class rescue treatment for patients suffering from Status Epilepticus in emergency situations



  III Strategic use of sales and promotional resources to drive ZEPIZURE® utilization and adoption as the new Standard of Care (SOC) for epileptic seizure in rescue situations



BARDA UP TO \$155M AWARD AND COLLABORATION*



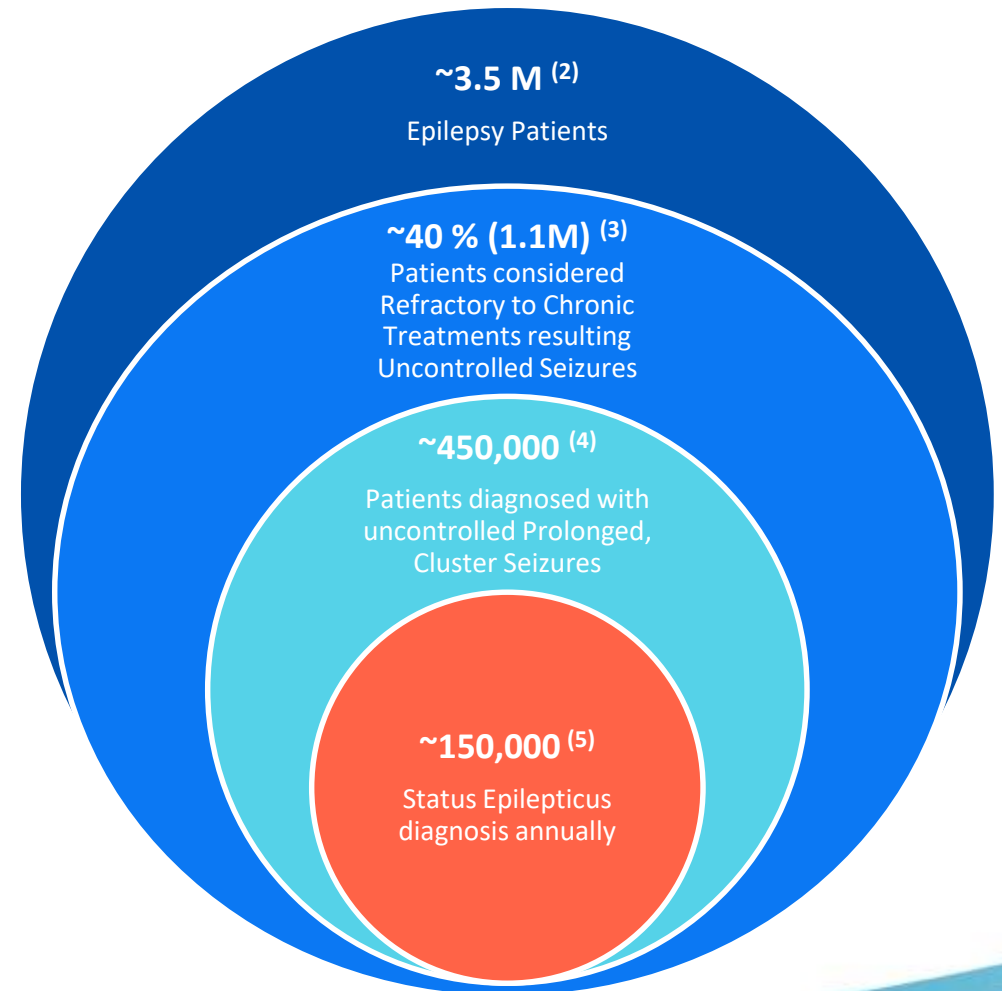
- **Biomedical Advanced Research & Development Authority** provides an integrated, systematic approach to the development of vaccines, drugs, therapies, and diagnostic tools for **public health medical emergencies** such as **chemical**, biological, radiological, and nuclear (CBRN) **accidents, incidents and attacks**; pandemic influenza (PI), and emerging infectious diseases (EID)
- CROSSJECT award* announced June 2022
- Up to **\$32M** for the advanced development of ZEPIZURE® through regulatory approval by the FDA for the treatment of status epilepticus seizures in adults and children over the age of 2
- **>\$15M** in costs reimbursement **since June 2022**
- Biweekly meetings with BARDA Project Coordinating Team
- Delivery of ZEPIZURE® to the U.S. Government will initiate once **Emergency Use Authorization (EUA)** from the FDA is granted
- **Firm order \$60M** upon approval and additional order options for \$59M
- Other options for \$3M



STATUS EPILEPTICUS




- FDA Rare Disease designation - No current Rx
- Up to 30% of epilepsy patients ultimately diagnosed with Status Epilepticus ⁽¹⁾
- Significant life threatening and medical risk
- Uncontrolled seizure >5 mins place neurons at risk and risk of death increases by 20%

US Epilepsy Patient Populations



US EPILEPSY SEIZURE RESCUE MARKET – KEY COMPETITORS



	ZEPIZURE® (NF Midazolam)	Nayzilam® (nasal Midazolam)	Valtoco® (nasal Diazepam)
Device			
Status Epilepticus FDA Indication	First NDA Filing ✓	✗	✗
Common Epilepsy Seizure Control (i.e. Seizure Clusters, Repetitive, Atypical)	Second NDA Filing ✓	✓	✓
Patient Age FDA Labeling	Adult first NDA, ✓ Pediatric NDA to follow	12+ Years of age	2+ Years of age
Dose Variation reduced by the Gold Standard IM Injection Drug Delivery	✓	✗	✗

~1.1M
Refractory
patients with
uncontrolled
seizures ⁽¹⁾

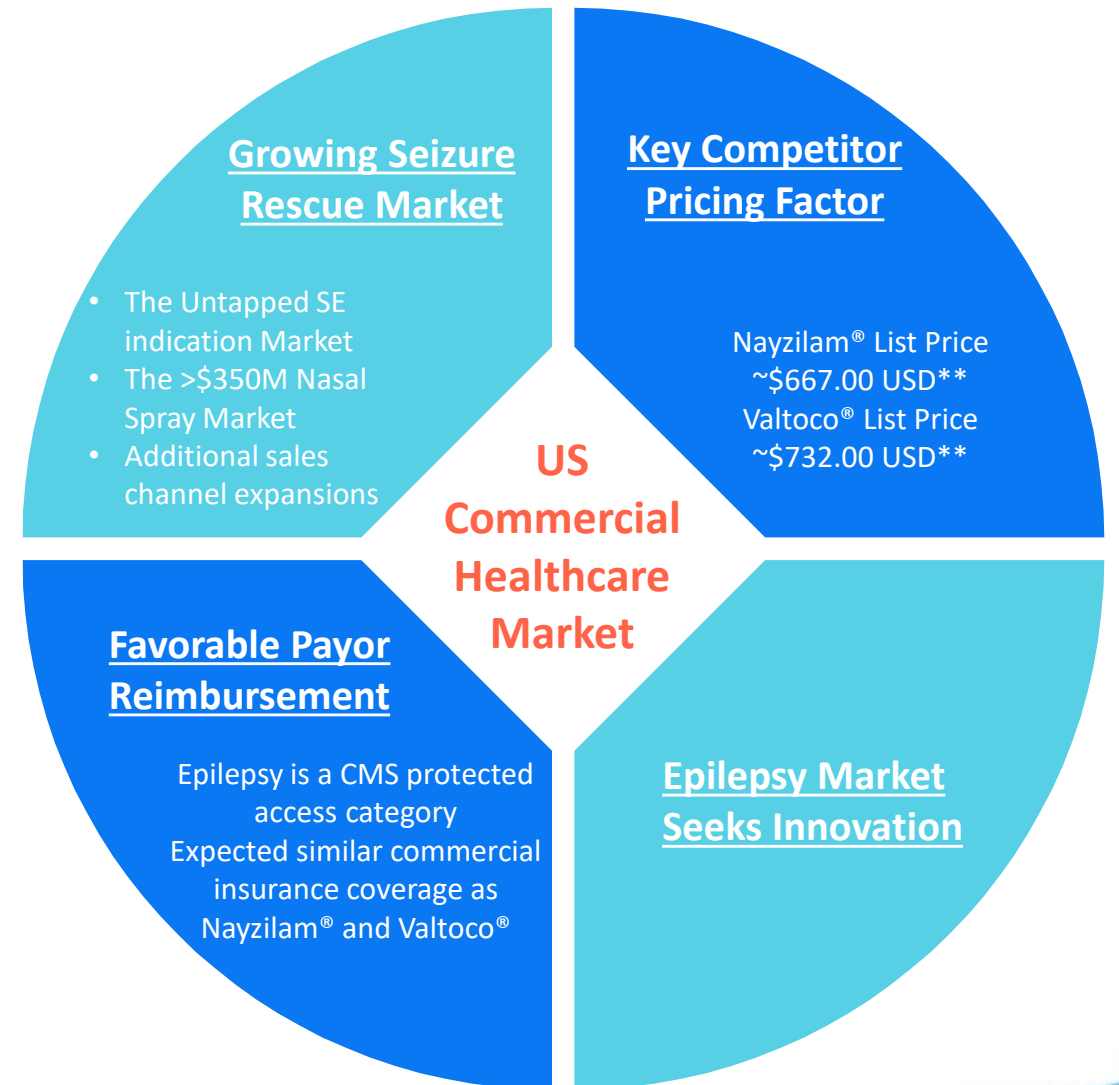
~300 Epilepsy
Treatment
Centers across
44 states ⁽²⁾

~2450 US Epilepsy
Specialist –
~1900 are board
certified
epileptologist ⁽³⁾

US Government Stockpiling



Confirmed \$60M order*
+
Additional optional \$59M order*



ZEPIZURE® FDA REGULATORY PATHWAY - EUA



Pre-EUA Meeting	Agreement on the EUA dossier content (clinical studies, CMC minimal requirements)	
Type C consultation on device	Presentation of ZENEO functions, manufacturing process, quality and controls	
CMC (<i>Chemistry, Manufacturing, and Controls</i>) Compliance	6 months stab data from 1st GMP batch Validation batches in Q1/2-2025	
Non Clinical, Clinical & Human Factor Studies	Completed	
EUA Submission & FDA Review	CROSSJECT & BARDA – Detailed review started Short review timelines (3-months anticipated)	
First delivery to BARDA	Delivery expected from Q3-2025	

ZEPIZURE® FDA REGULATORY PATHWAY - NDA 505(b)(2)



Development Plan	Completed for Status Epilepticus Aligned with FDA (continuation of the EUA)	
Type C consultation on device	Same as EUA	
CMC (Chemistry, Manufacturing, and Controls) Compliance	Same as EUA, with longer stability data	
Non Clinical, Clinical & Human Factor Studies	Clinical bioequivalence study vs US reference drug 2025 Human factor study for 1-unit pack 2025	
NDA Submission & FDA Review	Same dossier as EUA, with additional clinical data Expedited review will be requested	
Commercial batches	Start H2 2026	

ACUTE ANAPHYLAXIS

PREVALENCE

- 200K cases of Anaphylaxis each year ⁽¹⁾
- 8% of US adults experience such crisis (~16m) ^(2;3)

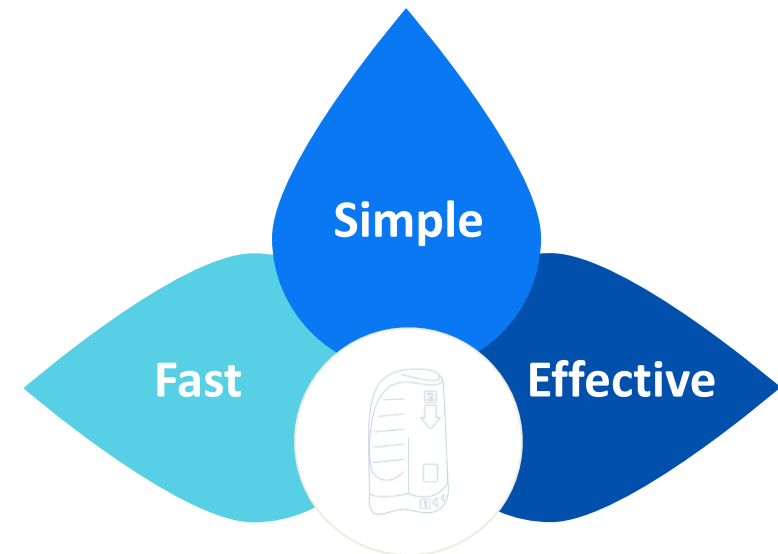
UNMET NEED

- Onset of life-threatening symptoms requires immediate rescue treatment, often by untrained caregivers
- Patients seeking needle-free treatments or suffering from needle-phobia
- Improved self-treatment devices that offer improved drug delivery, portability, easy of use, economic value, shelf-life

CURRENT & SOC

- IM epinephrine auto-injectors are current Standard of Care (SOC)
- 5.2m 2-pack sold per yr. in the US ⁽⁴⁾
- New nasal epinephrine treatment recently launched – Neffy - ARS Pharma

Simple 2-step administration
First-time user success rate as high as 99.6% in Company human factors testing, no formal training



Unpacking & Administration requires <60 secs

Needle-free “Quick-Click” injection takes 1/10th of a second for full dose...traditional needle/syringe are typically 3-10 secs injections

IM Epinephrine injections and auto-injectors are preferred efficacious SOC

Needle-free injection may reduce dose variability and ensure drug delivery in crisis events

ACUTE ADRENAL CRISIS

PREVALENCE

- Global prevalence 4,9/10,000 ⁽¹⁾
- US cases ~ 100,000 ⁽²⁾ annually

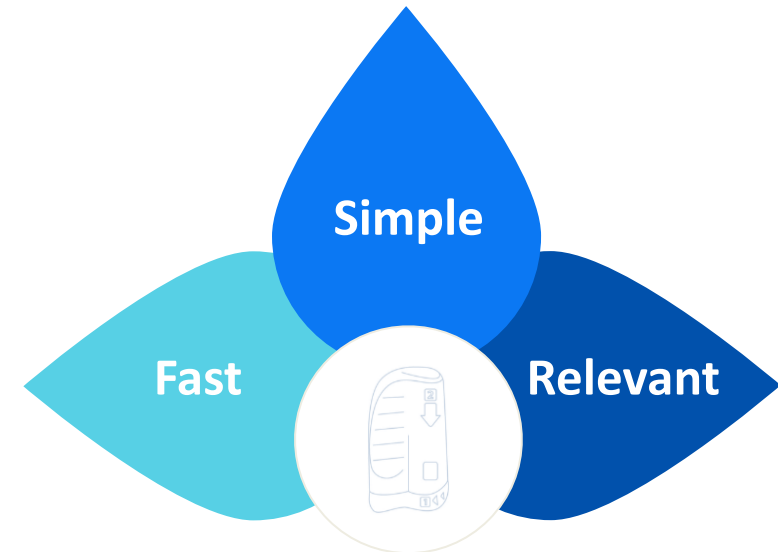
UNMET NEED

- Life-threatening symptoms require immediate rescue treatment
- 1/3 of crisis events occur outside home ⁽³⁾
- 65% of patients wait for caregiver ⁽³⁾ assistance
- 46% of patients receive Hydrocortisone beyond recommended time limit ⁽⁴⁾

CURRENT & SOC

- IM Hydrocortisone is current Standard of Care (SOC)
- Solu-cortef® 12 steps to injection & kit to be assembled - Pfizer

Simple 2-step administration
First-time user success rate as high as 99.6% in Company human factors testing, no formal training



Unpacking & Administration requires <60 secs

Needle-free "Quick-Click" injection takes 1/10th of a second for full dose...traditional needle/syringe are typically 3-10 secs injections

IM Hydrocortisone injections are preferred over oral hydrocortisone due to PK profile

Needle-free injection may reduce dose variability and ensure drug delivery in crisis events

PIPELINE AND NEAR-TERM VALUE CREATION

	Development Progress Formulation & CMC / Human Factor studies / Regulatory studies	Filing	Targeted Filing Date	Expected Commercial Launch	Partner / Sponsor
ZEPIZURE®					
US - Emergency Use Authorization (EUA)		EUA	Early-25	2025	
US - Status Epilepticus (SE)		NDA 1	Mid-25	2026	
US - Prolonged Seizures		NDA 2	Mid-26	2027	
Europe			H2 25	2026	Undisclosed
Australia/NZ			H2 25	2026	
ZENEO® Hydrocortisone					
US			2025	2026	
Europe			2025	2026	
ZENEO® Adrenaline/Epinephrine	 		2026	2027	To be defined
Future ZENEO® products			-	-	

* Contract no: 75A50122C00031 with the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Research and Development Authority

FINANCIALS AND INVESTORS



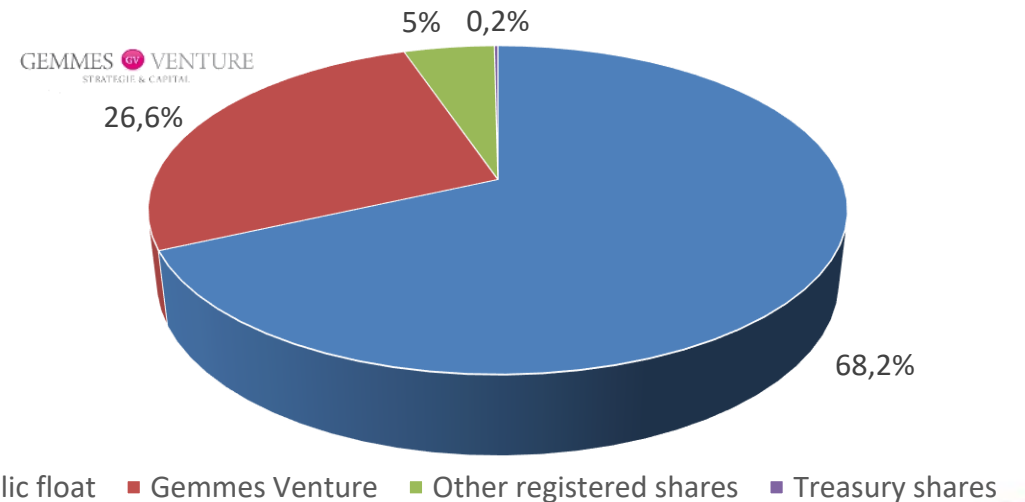
DIVERSIFIED FINANCIAL RESOURCES



Analyst Coverage



Shareholders ⁽¹⁾ (as of 13 December 2024)



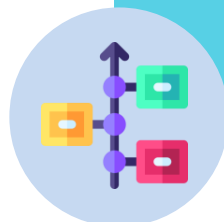
CROSSJECT - AN EMERGING GLOBAL PHARMACEUTICAL COMPANY

Unique foundational technology and validated ZENEO® needle-free auto-injector

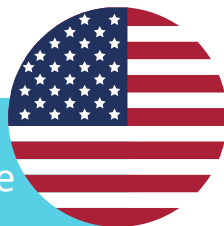


3 focus Rx products

Epilepsy: ZEPIZURE®
Acute Anaphylaxis
Acute Adrenal Crisis



Growing US presence to accelerate commercialization of ZEPIZURE® in the US Epilepsy markets



Sales to BARDA expected to begin in 2025

CONTACT

Investor relations

investors@crossject.com



A large, semi-transparent version of the CROSSJECT logo is overlaid on the right side of the image. It is positioned over a woman's arm and hand, which is resting on her hip. The woman is wearing a blue dress with a white star pattern. The background is a light blue gradient.

www.crossject.com

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info@crossject.com

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- **Slide 20 :**
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- **Slide 21 :**
 1. Calculated from Broersen, Smans, Olafsson and van der Kamp
 2. Source: Eton Pharma press release
 3. White, 2010, European Journal of Endocrinology (2010)
 4. Hahner, 2015 Clin. Endocrinol. 2015;82(4):497-502

- **Slide 24 :**
 1. On a primary diluted basis. Management holds ~2.7% of the share capital on a fully diluted basis

Additional Sources: World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH)

APPENDIX



AN EMERGING GLOBAL PHARMACEUTICAL COMPANY - BUSINESS STRATEGY



CROSSJECT mainly targets US and European markets*

* Depending on the country indication, licensing and partnership could be preferred (Epilepsy Europe : Undisclosed, Adrenal Insufficiency : Eton Pharmaceuticals)

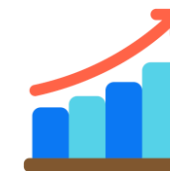


Key markets :
Distribution made by our teams



Rest of the World

Out-licensing and
Partnership



Further development of
other drugs according
to medical needs :
**ZENEO® can be adapted
for dozens of molecules**

CROSSJECT KEY MANUFACTURING EQUIPMENT



Tubes Forming



Thermal Toughening of Tubes



Dimensional Control of Components



Tubes Forming

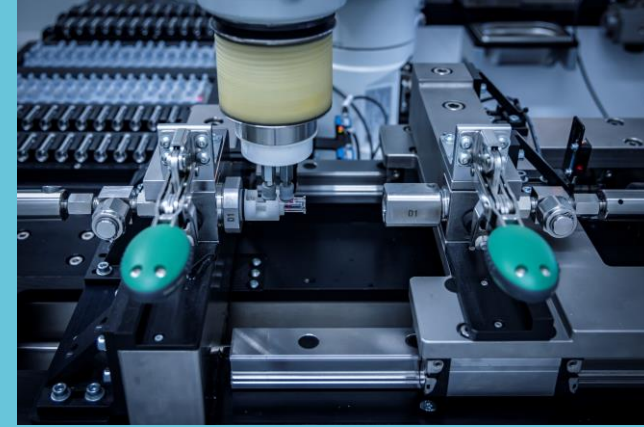


Gas Generator Manufacturing

CROSSJECT KEY MANUFACTURING EQUIPMENT



Final Quality Control



Mechanical Resistance of Tubes



Actuators Assemble



Depyrogenation of tubes

ZEPIZURE® - PROVEN BIOEQUIVALENCE



ZEPIZURE® Bioequivalence

(vs. Midazolam 2 mL, 10mg IM needle injection)



ZEPIZURE® Delivery Bioequivalence

(bare skin vs. through clothing)



ZEPIZURE® Safety

(Similar adverse events profile)



ZEPIZURE® Fast onset with low dosage variability

(Similar to IM injection with 30mm needle injection)



Qualifying for FDA EUA process and Europe MAA

KEY FINANCIAL RESULTS FOR H1 2024



INCOME STATEMENT, H1 FY 2024

<i>(Thousands of euros)</i>	30/06/2024	30/06/2023
Operating income	5 766	7 926
BARDA income	3 063	2 987
Capitalized Production	1 565	3 017
Work in progress	354	77
Other income	784	1 846
Operating expenses	-12 485	-14 461
Purchase of raw material and supplies	-695	-576
Other purchases and external expenses	-5 005	-4 456
Personnel expenses	-3 950	-4 098
Taxes and duties	-100	-120
Depreciation, amortisation and provision	-2 517	-4 952
Other expenses	-218	-258
Operating profit/loss	-6 719	-6 535
Financial income/expense	-994	-263
Exceptional income/expense	-330	585
Research tax credit	1 641	1 651
Net profit/loss	-6 402	-4 562

BARDA INCOME

- Consolidation of BARDA's operating income. We invoiced BARDA \$3,3M for the first half of 2024, in continuity with \$3,2M for the first half of 2023.

STABLE OPERATING PROFIT AND LOSS

- The variation in operating income and expenses is mainly attributable to the change in the valuation of R&D capitalized at the end of the 2023 financial year (cf. Annual Financial Report, p. 12).
- Stable investment in the R&D.

NET RESULT

- No variation due to operations.
- Variation mainly due to depreciation of securities.

BALANCE SHEET, 30 JUNE 2024 VS. 31 DECEMBER 2023

BALANCE SHEET - ASSETS (in K€)	30/06/2024			31/12/2023	VARIATION
	Brut	Amts & prov	Net		
FIXED ASSETS					
R&D	36 521	26 283	10 238	10 730	-492
Patent and Trademarks	20 440	20 440	0	0	0
Other intangible assets	206	206	0	0	0
Land, property, plant and equipment	10 523	8 283	2 240	2 750	-510
Assets under construction	3 821		3 821	2 942	879
Financial assets	1 801	805	996	1 544	-548
TOTAL FIXED ASSETS	73 312	56 017	17 295	17 966	-671
CURRENT ASSETS					
Raw materials, other supplies	2 116	95	2 021	1 648	373
Work in process	2 783	419	2 364	1 485	879
Other receivables	4 066		4 066	4 778	-712
Marketable securities			0	0	0
Available cash	5 952		5 952	2 304	3 648
Prepaid / deferred expenses	1 430		1 430	460	970
TOTAL CURRENT ASSETS	16 347	514	15 833	10 675	5 158
TOTAL ASSETS	89 659	56 531	33 128	28 641	4 487

BALANCE SHEET, 30 JUNE 2024 VS. 31 DECEMBER 2023

BALANCE SHEET - LIABILITIES (in k€)	30/06/2024	31/12/2023	VARIATION
EQUITY			
Capital	4 109	3 676	433
Share premium	110	785	-675
Regulated reserve	0	0	0
Retained earnings	-2 596	-1 757	-839
Profit/loss for the year	-6 402	-8 639	2 237
Investment subsidies	665	665	0
TOTAL SHAREHOLDERS' EQUITY	-4 114	-5 270	1 156
Conditional advances	5 878	7 060	-1 182
Provision for contingencies and charges	739	694	45
BORROWINGS AND DEBTS			
Bonds	6 738	19	6 719
Loans	14 526	16 171	-1 645
Miscellaneous	2 721	2 741	-20
Debts - Trade payables	4 458	4 323	135
Total tax ans social security liabilities	1 510	2 148	-638
Debts on fixed assets	0	83	-83
Deffered income	672	672	0
TOTAL DEBT	30 625	26 157	4 468
TOTAL EQUITY AND LIABILITIES	33 128	28 641	4 487