



*A company selected as a France 2030 laureate*

## **From a rare-disease clinical validation to blockbuster market authorization**

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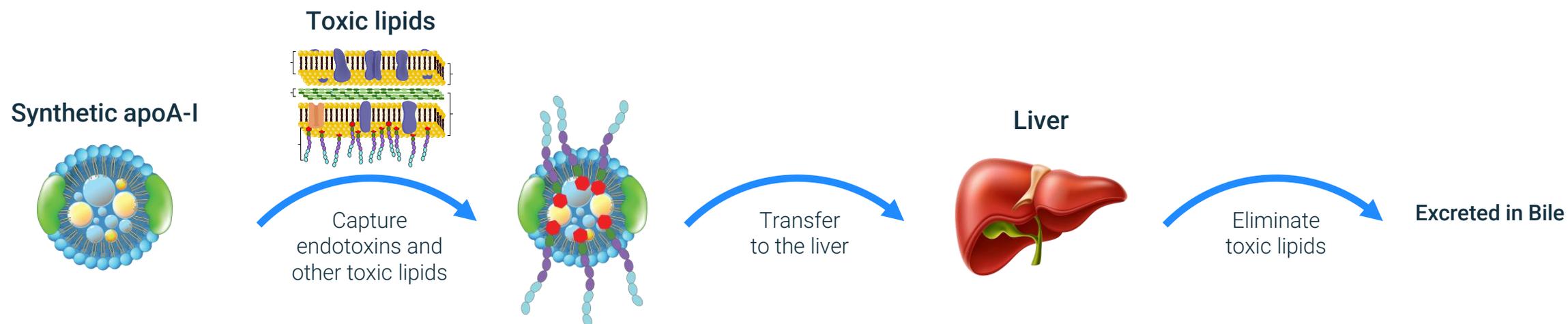
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# Abionyx: Global leader in recombinant apoA-I with transformative clinical efficacy

- 1 Global leader in **recombinant human apoA-I** therapies, leveraging over 20 years of lipid metabolism expertise to pioneer the first bioengineered therapy for toxic lipids regulation
- 2 De-risked regulatory pathway for **ultra-rare LCAT deficiency**, having already demonstrated clinical success through compassionate use across four European countries and securing Orphan Drug Designation in both the US and EU
- 3 Targeting the world's 3rd leading cause of death, the RACERS **Phase 2a study in Sepsis** demonstrated **practice changing clinical results**: 65% reduction in 30-day mortality risk, 71% drop in ICU mortality, and 5-day shorter ICU stay versus control
- 4 **Proprietary industrialized bio-production** site utilizing a robust and patented bioprocess to ensure high-quality, scalable global supply for upcoming clinical trials and regulatory submissions
- 5 Following EMA acceptance of a shortened 2-batch validation process, the company is preparing for a **Marketing Authorization Application** (MAA) in LCAT while targeting a 2026 Phase 2 sepsis trial start (subject to financing)

# We developed the first bioengineered apoA-I, a breakthrough innovation in toxic lipid regulation

Abionyx is producing **CER-001**, a human HDL/apoA-I, one of the most abundant protein in human blood, identical in structure and function, overcoming challenges of stability, purity, and large-scale manufacturing.

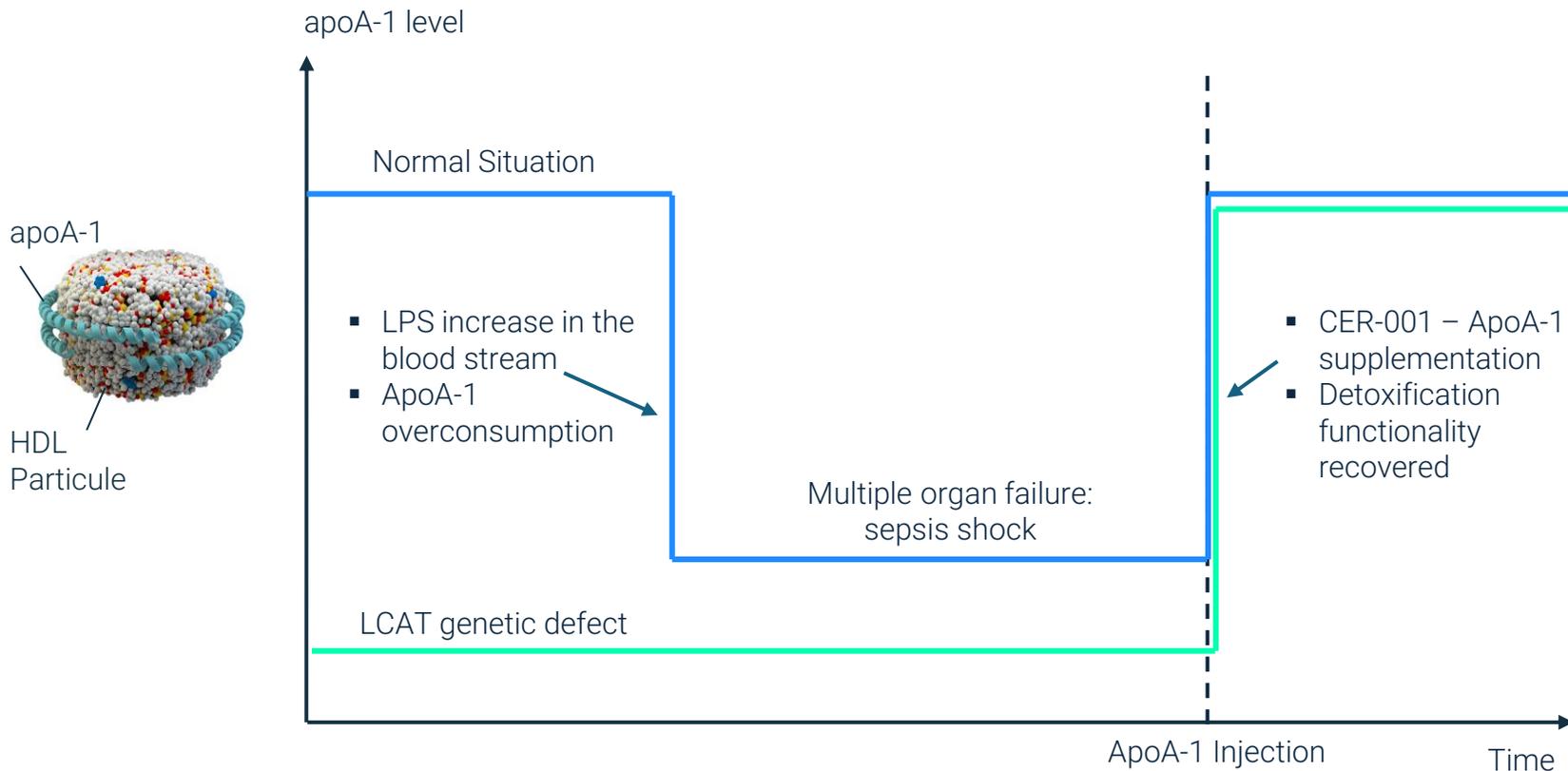


## Why is it a breakthrough?

- A multi-benefit action — addressing tissue damages, decreasing inflammation, leading to fast recovery
- Works across many diseases
- No known risk of drug resistance

# CER-001 biotherapy targets the root cause shared by two diseases

Both **LCAT deficiency** (genetic, chronic) and **Sepsis** (acute) lead to a loss of apoA-I, the key complex that clears toxic lipids and controls inflammation. Abionyx is advancing therapies addressing these two indications.



**Sepsis: Low level of apoA-1 due to over consumption**  
ApoA-1 depleted acutely

**LCAT: Non-functional HDL/apoA-1 due to inherited genetic defect**  
HDL-apoA-1 depleted chronically

- CER-001 – ApoA-1 supplementation
- Detoxification functionality recovered

# Proven GMP manufacturing process ready to commercial roll-out

Since its first successful production in 2015, Abionyx has completed more than **35 batches** of CER-001 – the latest in early 2025 – leveraging a France-based **network of leading CDMOs**.



UPSTREAM PROCESS



**Cell culture**  
Crude apoA-I



DOWNSTREAM PROCESS



**Purification**  
98% Pure apoA-I



COMPLEXATION



**Complexation and Fill & Finish**  
Homogeneous HDL population 100% yield

This vertical integration strengthens Abionyx’s control over **manufacturing quality regulatory alignment**, and **supply reliability**



Biological properties | **Full-length protein apoA-I**

More stable | **Stability up to 8 years with French authorities**

Molecule crossing the Blood Brain Barrier | **10 nm**

Cold storable at positive temperature | **2 to 8°C**

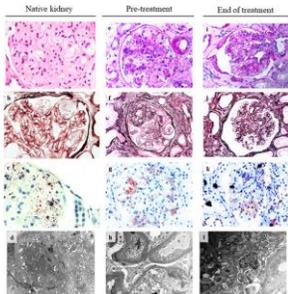
Ultra-pure | **>99%**

Optimized structure | **Pure Synthetic SpingoMyelin**

# Pipeline overview

Candidate	Indication	Preclinical	Phase I	Phase II	Phase III	MAA	Comments
CER-001	LCAT						<ul style="list-style-type: none"> <li>2 GMP batches to be manufactured in 2026/2027</li> <li>EMA submission in 2027 and FDA submission in 2029</li> </ul>
CER-001	Sepsis						<ul style="list-style-type: none"> <li>Phase 2b to be started in 2026</li> </ul>
ABNX-100	Ophthalmology / Uveitis						<ul style="list-style-type: none"> <li>Next steps in 2026/2027</li> </ul>

# Clinical development completed for LCAT deficiency, a severe disease with no existing treatment



Rare genetic disease leading to loss of functional HDL/apoA-I and progressive organ failure: kidney, eye, anemia

0 approved treatment

€200 M market opportunity

1 K+ estimated patients worldwide

4 ODD from EMA & FDA

✓ Outstanding positive clinical results where all 8 patients were responsive to treatment - Sept 2024.

Clinical Development



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Biomanufacturing (CMC)

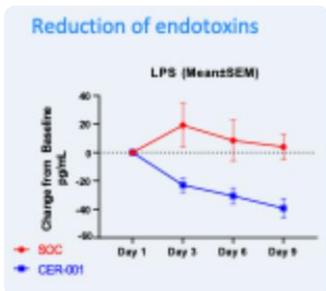
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Market Authorization

Only 2 validation batches needed to file for approval  
To be filed by 2027

expected filing in 2027  
for a market authorization in 2028

# Outstanding Phase 2a outcomes set a solid foundation for the upcoming Phase 2b



Sepsis is a life-threatening immune overreaction that causes organ failure. Third leading cause of death worldwide, it often follows infection or occurs during epidemics, natural disasters, and wars

**0** authorized therapy addressing the root cause

**€27 B** market opportunity

**11 M** death per year worldwide

**Endotoxins** (LPS) major root cause

## The Phase 2a RACERS study

Late breaker ASN  
 CER-001 + Standard of care vs Standard of care alone  
 20 patients

**65% reduction in 30-day mortality risk** (6.7% mortality for CER-001 vs 20% for standard of care)

**71% drop in ICU mortality** (14.7% mortality vs 50% for standard of care)

**5-day shorter ICU stay** (vs control)

### Clinical Development

Entering a Phase 2b Sepsis trial with *FDA-backed* adaptive design

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### Biomanufacturing (CMC)

Proven GMP process and validated CMC from LCAT indication will make **CMC regulatory approval** simpler for Sepsis

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### Market Authorization

Active engagement with FDA & EMA to accelerate approval through *Fast Track* and *PRIME* pathways, **targeting a 2031 launch** – up to four years faster than standard timelines

# A study in Scientific Reports in NATURE demonstrates that higher genetically predicted plasma apoA-I causally protects against sepsis incidence and 28-day mortality



Publication of the study in Nature Portfolio’s Scientific Reports on October 21, 2025

Mechanistically, **apoA-I neutralizes pathogen lipids** and modulates signalling to blunt cytokine storms and preserve endothelial integrity, providing both a genetically validated target and a clear therapeutic rationale for apoA-I–based interventions in sepsis

ApoA-I, the main structural protein of HDL, **binds pathogen lipids (e.g., LPS) and neutralizes pro-inflammatory stimuli**, a direct biochemical action that plausibly links higher apoA-I to reduced systemic inflammation in sepsis

## Key advantages and value drivers for ABIONYX Pharma:

- ApoA-I is the functional core of HDL’s protective role in infection
- Quantitative magnitude is clinically meaningful
- Genetic causality materially reduces biological risk, which is important for regulators and supports mechanistic link to potential therapeutic modalities

# IHU SEPSIS is the World's Leading Center Dedicated to Sepsis to create the first fully integrated global platform dedicated to the treatment of sepsis



ABIONYX Pharma entered into advanced strategic discussions with IHU SEPSIS to partner on sepsis treatments on November 11, 2025

A **world-class hub** to integrated research, education, and patient care for innovation across pediatric and adult sepsis **60 research teams** (275 researchers and 94 clinical physicians), patient associations and world-class hospitals through organizations such as the **Global Sepsis Alliance and Sepsis Canada**

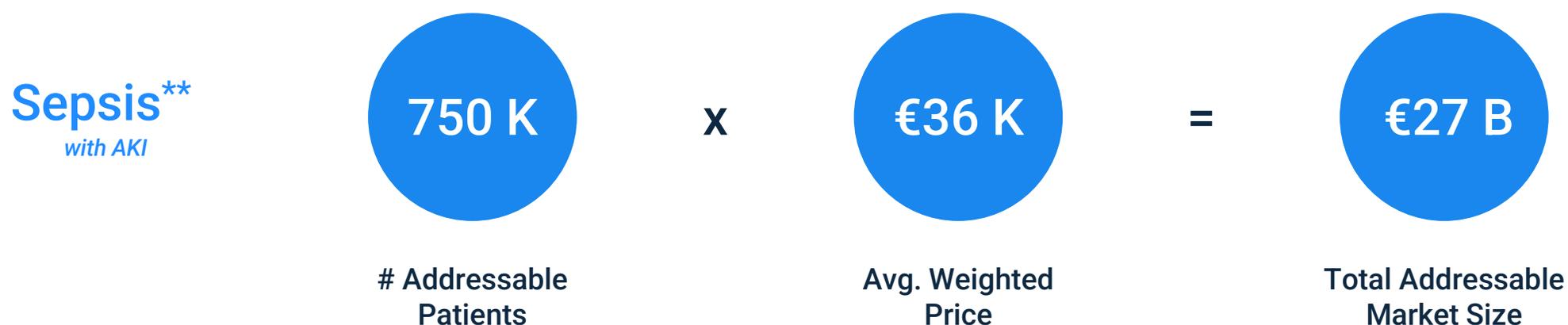
**Extensive international network** to deploy multi-country clinical protocols and studies with leading hospitals in the United States, Canada, Europe, and emerging regions

## Key advantages and value drivers for ABIONYX Pharma:

- Clinical development speed and cost related to world hospital centers network
- Direct connections with expert centers and access to biobanks to document the natural history of the disease
- Scientific visibility to involve patient associations
- Reinforced corporate and scientific reputation through collaborations with recognized KOLs and reference institutions

MARKET SIZE

# While LCAT secures a niche market opportunity, Sepsis unlocks the **multi-billion-euro upside**



\* Total number of addressable patients worldwide

\*\* Number of addressable patients per year for US, Canada and Europe market

Sources: Mehta R. et al., Orphanet J Rare Dis. 2021;16:448 – StatPearls, 2024

– Orphanet (Expert #313, 2023) – MedlinePlus Genetics.

TEAM

# A leadership team with strong equity ownership and recognized scientific and business achievements



**Cyrille Tupin**  
CEO  
pwc



**Dr Rob Scott MD**  
CMO, head of R&D  
abbvie AMGEN



**Connie Keyserling Peyrottes**  
SVP of Clinical Development & Operations  
Pfizer ESPERION



**Margit Holzer, Ph.D.**  
SVP of Bio-production  
novasep BIONTECH



**Ronald Barbaras, Ph.D.**  
SVP of R&D  
Inserm



**Laurent Guerci**  
Chief Digital & Innovation Officer  
ACTIA



**Jérôme Martinez**  
Senior Advisor,  
Ophthalmology  
Santen



**Emmanuel de Fougeroux**  
CFO



**5 publications**  
with positive clinical results

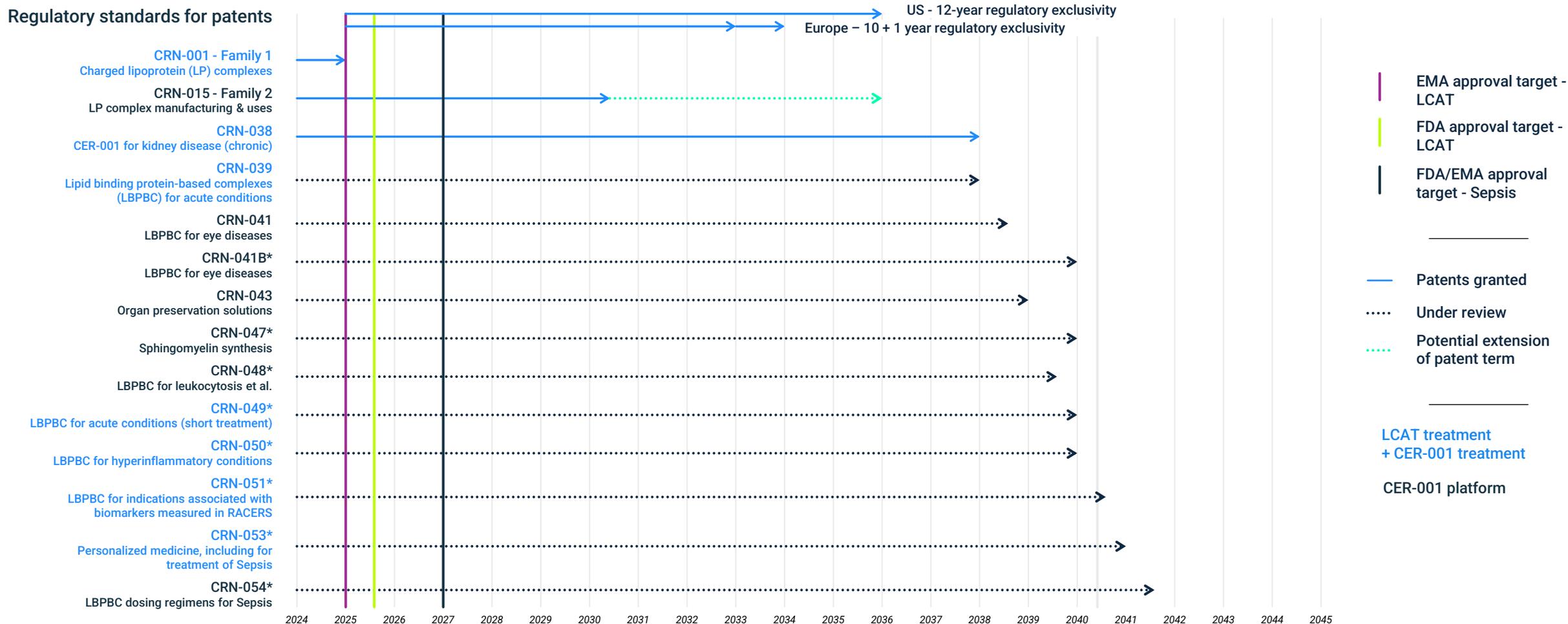


**France 2030 Laureate,**  
validating the project's quality through a rigorous national audit and providing an €8.7 M grant



**IP protected**  
Patent portfolio covering therapeutic and manufacturing innovations through 2042

# CER-001 is protected until 2042 plus the BLA protection for 10-12 years

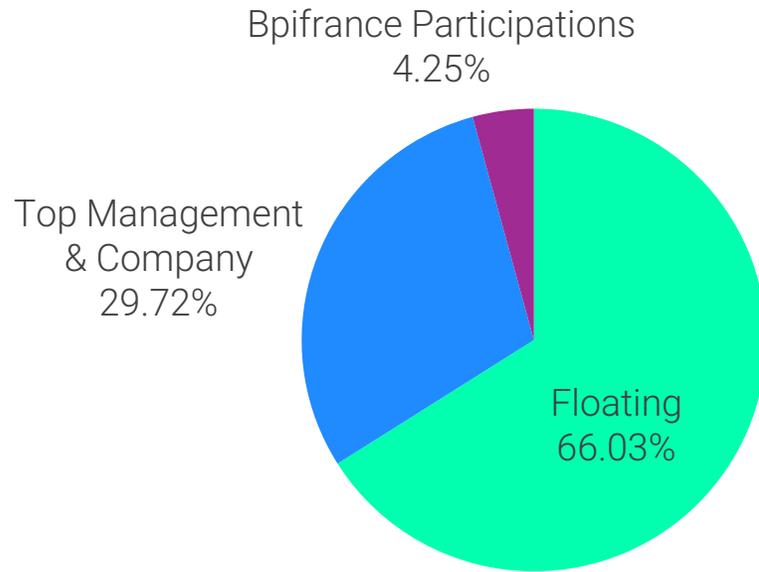


# A Euronext listed biotech with strong liquidity

## Abionyx (ABNX) – Equity Overview



### OWNERSHIP



### LIQUIDITY & MARKET DYNAMICS

**66 % free float**

**€1.3 M+ daily trading turnover<sup>1</sup>**

**PEA-PME eligibility** driving active French retail participation

**Tight spreads** and **consistent turnover**, making it attractive for small- and mid-cap equity funds

**Ticker / Exchange** ABNX, Euronext Paris

**ISIN** FR0012616852

**Listing & eligibility** PEA / PME eligible in France

**Latest Share Price** ~ €3.55

**52-Week Range** €1.09 – €5.29

**Shares Outstanding** 35.51 M

**Market Capitalization** ~ €126.1 M

**Free Float** ~ 66,03 %

**Recent Volume / Liquidity** Average daily volume ~ 350,000 shares<sup>1</sup>

Cash position of €2.8 M as of 30 September 2025

€1.8 M raised in December 2025

€6 M still to be received from France 2030 program

**Financial visibility until the end of 2026**

*Data as of 11<sup>th</sup> February 2026  
Note: (1) Over the last 6 months*



**Thank you.**