

# Crossject

Outperform → | Target price : 7.10 €

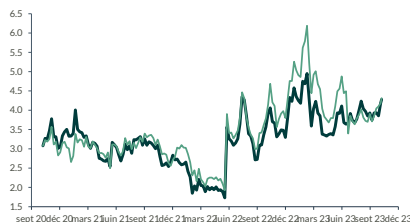
Price (06/11/2023): € 4.28 | Upside : 66%

Revision	12/23e	12/24e
EPS	ns	ns

## Needle-free device offers significant advantages

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Sources: ODDO BHF Securities, SIX

### Share data

ALCJ FP   ALCJ.PA	
Market Cap (€m)	159
Enterprise value (€m)	187
Extrema 12 months (€)	3.21 - 4.95
Free Float (%)	ns

Performance (%)	1m	3m	12m
Absolute	14.3	14.6	9.5
Perf. rel. Country Index	14.6	18.7	1.1
Perf. rel. Next Biotech	16.3	16.0	4.0

P&L	12/23e	12/24e	12/25e
Sales (€m)	1.9	42.9	48.3
EBITDA (€m)	-15.9	24.3	28.3
Current EBIT (€m)	-21.2	22.2	25.9
Attr. net profit (€m)	-21	16.6	19.4
Adjusted EPS (€)	-0.57	0.45	0.52
Dividend (€)	0.00	0.00	0.00

P/E (x)	ns	9.6	8.2
P/B (x)	ns	ns	9.1
Dividend Yield (%)	0.0	0.0	0.0
FCF yield (%)	ns	7.0	12.0
EV/Sales (x)	100.50	4.10	3.25
EV/EBITDA (x)	ns	7.2	5.5
EV/Current EBIT (x)	ns	7.9	6.0
Gearing (%)	ns	ns	-25
Net Debt/EBITDA (x)	-1.6	0.6	-0.2

### Next Events

Crossject is a biopharmaceutical company that manufactures a medical device coupled with a self-injectable drug. The group's expertise and the difference vis-à-vis its rivals lies in its needle-free ZENEO device. Developed for emergency treatment, we believe that the agreement signed with BARDA lends credibility to the entire platform and its clinical value. With a firm order for \$ 60m for its first candidate product ZENEO Midazolam, we expect the first sales from 2024 pending approval at end-2023/start of 2024. We also factor in the group's two priority candidates which will be launched on the market between 2024 and 2026 and see the rest of the clinical portfolio as free option. We initiate coverage of the stock with an Outperform rating and a target price of € 7.1.

### An innovative offering on a dynamic market

Crossject's offering is based on its ZENEO system, a needle-free, pre-filled, single-use auto-injector combined with a drug. Its main objective is to enable the rapid and precise administration of drugs through the skin or even through clothing, offering an effective alternative to injections with traditional needles. The injectable drug market represents more than 20% of the pharmaceuticals market, driven in part by auto-injection. We see this innovation as offering a real improvement in patient comfort and the assurance of an effective injection, particularly in emergency situations.

### Emergency treatments are the obvious target

Crossject made the strategic decision to focus primarily on so-called emergency indications. The company's late-stage pipeline comprises three assets, namely ZENEO Midazolam, Hydrocortisone and Adrenaline, used respectively in the treatment of epileptic seizures, acute adrenal insufficiency and anaphylactic shock. The compounds chosen are generic drugs with already proven efficacy, de-risking the clinical development. Unlike the development of a traditional pharmaceutical compound, we believe that the probability of clinical and then regulatory success is much higher for the development of a combination with ZENEO. We estimate peak sales at € 187m for ZENEO Midazolam, € 98m for ZENEO Hydrocortisone and € 341m for ZENEO Adrenaline.

### A transformative agreement with BARDA

In June 2021, Crossject won a tender launched by the US government via BARDA to supply, subject to the securing of marketing authorisation from the FDA, ZENEO Midazolam in the treatment of epileptic seizures for a contract worth up to \$ 155m. We expect approval to be secured by the end of the year/early 2024 in emergency treatment with the first orders launched in Q2 2024.

### Target price of € 7.1. Initiation at Outperform

We value the company using the sum-of-the-parts method. We base our calculations on the management's priorities, namely the ZENEO Midazolam, ZENEO Hydrocortisone and ZENEO Adrenaline combinations. We model separately the BARDA agreement, which is the group's absolute priority for the next twelve months. This deal hinges on securing approval for emergency use, which is expected before the end of the year/start of 2024. The risk in the short term could come from additional requests from the FDA before the combination is approved. Our target price works out at € 7.1 which represents upside of close to 66%. Initiation at Outperform.

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<b>Crossject</b>	<b>Outperform</b>	
Biotechnology   France	Target price:	7.10 €
Market Cap: € 159m	Price (06/11/2023):	€ 4.28

Company profile	Shareholders	
<p>Crossject is a biopharmaceutical company manufacturing a medical device coupled with a drug for self-injection. The group's expertise and the difference vis-à-vis its rivals lies in its ZENEO medical device which is needle-free, single-use, automatic, pre-filled and easy to use.</p>	Free float	52.90%
	Gemmes Venture	24.47%
	Vester Finance	12.18%
	Others	8.69%
	SNPE	1.76%

## Sales breakdown (2022)



## Investment case

The group's expertise and the difference vis-à-vis its rivals lies in its needle-free ZENEO device. Developed for emergency treatment, we believe that the agreement signed with BARDA lends credibility to the entire platform and its clinical value. With a firm order of \$ 60m for its first candidate, Zeneo Midazolam, we expect sales to start in 2024, pending approval by the end of the year. We only factor in the group's three priority candidates which will be launched on the market between 2024 and 2026 and consider the rest of the clinical portfolio as free option.

## SWOT

Strengths	Weaknesses
<ul style="list-style-type: none"> <li>- No real competitors</li> <li>- Rapid development</li> <li>- A first transformative contract signed with BARDA</li> </ul>	<ul style="list-style-type: none"> <li>- Not yet generating turnover</li> <li>- Apart from BARDA, no reference worldwide commercial partner</li> </ul>
Opportunities	Threats
<ul style="list-style-type: none"> <li>- Initial approval hoped for in the coming months for ZENEO Midazolam</li> <li>- A diversified portfolio in emergency treatment</li> </ul>	<ul style="list-style-type: none"> <li>- Refinancing to be expected to accelerate production capacity</li> </ul>



## ESG

Crossject's (evolving) CSR strategy already looks mature given its size (average headcount of 100 FTE in 2022). The Gaia ESG rating (arm of the Ethifinance group, specialised in the ESG rating of European SMEs and mid-sized companies) in 2023 stands at 73/100 (vs 60 in 2022 and 46/100 in 2021), reflecting a positive trend in the management of ESG themes, notably driven by a CSR steering committee. Xavière Castano, one of Crossject's co-founders, is in charge of CSR strategy.

On the social pillar - the most material for the sector in our view - the company seems to focus on questions of health and safety: a systematic analysis is conducted by the HSE team and a "corrective plan of action" is drawn up. Its efficacy is re-evaluated when the actions are deployed and the feedback is widely shared throughout the company. In 2022, Crossject reported 2 workplace accidents. Moreover, most of the social indicators point to a generally positive trend (training budget increased from € 76,000 in 2021 to € 85,000 in 2022, share of women employees increased to around 63% in 2022 and rise in the percentage of seniors). Gender equality, in particular in management, seems to be an area for improvement: one of the management board's four members is a woman and there are no women on the supervisory board.

As regards business ethics, the company has a relatively comprehensive system with 1/ a charter of ethics available on the website, 2/ a procedure for escalating red flags that is also open to the public (the company did not mention any red flags that were escalated in 2022). By the end of 2023, the company should integrate environmental and social indicators in its supplier audits.

On the environmental pillar (with a lower relative materiality for the sector), the company has an evolving policy that makes sense in our view. In particular, it carries out an environmental impact study on ZENEO, which comprises 58% Zamack, a fully recyclable material.

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# INITIATING COVERAGE AT OUTPERFORM WITH A TARGET PRICE OF € 7.1

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*Crossject is a biopharmaceutical company that manufactures a medical device coupled with a drug for self-injection. The group's expertise and the difference vis-à-vis its rivals lies in its ZENEO medical device which is needle-free, single-use, automatic and pre-filled. Crossject's strategy is to begin by targeting emergency treatments with the administration of an injectable generic drug: anaphylactic shocks, epileptic seizures, acute migraine headaches, etc.*

*The advantages that set ZENEO apart are its guaranteed administration efficacy, improved safety and comfort. The recent recognition in the US leading to a firm order of \$ 60m from BARDA, the Biomedical Advanced Research and Development Authority, confirms our positive view on the stock.*

This recognition has enabled the company's stock, although still trading below the level of its 2014 IPO, to benefit from positive momentum since the announcement of the agreement (+235%). In the short term, catalysts such as the granting of emergency use authorization and the receipt of a first BARDA payment should help maintain this momentum.

*Based on a sum-of-the-parts valuation, we have a target price of € 7.1 on the stock and an Outperform rating.*

## **Financial visibility out to mid-2024 but Capex to be extended to achieve its objectives**

At the end of H1 2023, Crossject had € 5.4m in cash. With a cash burn of € 15m per year, we think that the company has financial visibility out to mid-2024 factoring in non-dilutive financing.

The management has already partly consolidated the group's cash position with the receipt of non-dilutive financing in recent months (loans granted for periods of 5 to 10 years).

However, we believe that operating costs are likely to accelerate in line with the development of the company's pipeline and the company's strategic ambitions over the next 12-18 months: 1/ securing approval for emergency use, filing and first sales of ZENEO Midazolam for BARDA, 2/ clinical trials and filing for ZENEO Hydrocortisone and 3/ industrial transposition, clinical trials and filing of ZENEO Adrenaline.

The short-term challenges are therefore clinical (even though the risk is very limited), regulatory and above all industrial. We think that the company will therefore have to strengthen its cash position to achieve all of its targets.



Earnings estimates									
€ m	2018	2019	2020	2021	2022	2023	2024e	2025e	2026e
Revenue	0.00	0.50	0.00	0.91	0.95	0.00	41.02	46,40	32,17
Stored production	0.65	0.02	0.68	0.17	0.35				
Capitalised production	2.42	3.92	4.62	5.38	6.10				
Subsidies	0.02	0.48	0.22	0.19	0.01				
Reversals of provisions and transfers of expenses	0.43	0.07	0.18	0.10	0.45				
Other income	0.00	1.00	0.02	0.02	1.86	1.86	1.86	1,86	1,86
<b>Operating income</b>	<b>3.52</b>	<b>5.99</b>	<b>5.73</b>	<b>6.77</b>	<b>9.72</b>	<b>1.86</b>	<b>42.88</b>	<b>48,26</b>	<b>34,03</b>
Y-o-y change		70%	-4%	18%	43%	-81%	2204%	13%	-29%
Purchases of raw materials and other supplies	0.00	0.00	0.90	1.14	1.00	0.00	0.74	1,51	7,70
Change in inventory (raw materials and other supplies)	0.00	0.00	0.08	-0.19	-0.51	0.00	0.00	0,00	0,00
Other purchases and external expenses	7.66	6.39	4.89	5.90	8.12	7.60	7.60	6,55	4,25
Taxes and duties	0.13	0.14	0.20	0.20	0.18	0.00	0.00	0,00	0,00
Personnel expenses	3.97	4.31	5.33	6.18	7.43	10.20	10.20	11,86	10,00
Depreciation, amortisation	2.97	3.65	3.95	4.49	5.26	5.26	2.14	2,41	1,70
% as of sales	84%	61%	69%	66%	54%	3%	5%	5%	5%
Other provisions	0.36	0.15	0.61	0.52	1.10	0.00	0.00	0,00	0,00
Other expenses	0.00	0.00	0.45	0.34	0.43	0.00	0.00	0,00	0,00
<b>Operating expenses</b>	<b>15.08</b>	<b>14.64</b>	<b>16.40</b>	<b>18.60</b>	<b>23.01</b>	<b>23.06</b>	<b>20.69</b>	<b>22,34</b>	<b>23,66</b>
<b>Operating profit/(loss)</b>	<b>-11.56</b>	<b>-8.64</b>	<b>-10.67</b>	<b>-11.82</b>	<b>-13.29</b>	<b>-21.20</b>	<b>22.20</b>	<b>25,93</b>	<b>10,38</b>
Y-o-y change		25%	-23%	-11%	-12%	-60%	205%	-17%	60%
% as of sales	-328%	-144%	-186%	-175%	-137%	ns	52%	54%	30%
Financial income/(expense)	-0.74	0.11	-0.25	-0.88	-0.32	0.00	0.00	0,00	0,00
Exceptional income/(expense)	-0.01	0.02	-0.57	0.08	0.23	0.00	0.00	0,00	0,00
Employee profit sharing	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0,00	0,00
Research tax credit	1.59	1.34	1.65	1.82	2.22	0.00	0.00	0,00	0,00
<b>Net profit/(loss) before tax</b>	<b>-10.71</b>	<b>-7.18</b>	<b>-9.84</b>	<b>-10.81</b>	<b>-11.16</b>	<b>-21.20</b>	<b>22.20</b>	<b>25,93</b>	<b>10,38</b>
Income tax	0.00	0.00	0.00	0.00	0.00	0.00	5.55	6,48	2,59
Tax rate	25%	25%	25%	25%	25%	25%	25%	25%	25%
<b>Net profit (loss)</b>	<b>-10.71</b>	<b>-7.18</b>	<b>-9.84</b>	<b>-10.81</b>	<b>-11.16</b>	<b>-21.20</b>	<b>16.65</b>	<b>19,45</b>	<b>7,78</b>

Table 1 - Source: ODDO BHF Securities

## WCR and Capex will have to keep up

As H1 2023 showed, the company is readying to move forward in parallel on the clinical, production and regulatory fronts. The working capital requirement is therefore set to increase in the coming quarters. The variation amounted to € 2.3m in the first half due to an increase in stocks and customer receivables. It should be noted that BARDA has now become a Crossject customer and is included among its receivables.

This increase in the WCR is accompanied by an increase in Capex to at least cover the contract signed with BARDA. Crossject works both with subcontractors for the manufacturing of components and delivers products to a contract manufacturer for the filling of injectable sterile products. Crossject supplies the contract manufacturer with ready-to-fill kits (cf. chapter on industrialisation). To date, production capacity stands at 500,000 kits per year and is expected to increase to 6 million kits by 2028. For example, the firm order from BARDA is for 360k units with an option for an additional 416k.

Estimates for sales volumes by indication as of 2025					
Volume	2025e	2026e	2027e	2028e	2029e
ZENEO Midazolam	73	183	367	552	739
ZENEO Hydrocortisone	4	12	26	52	86
ZENEO Adrenaline	-	121	363	728	1 095
BARDA agreement	180	180		208	208
<b>Total (000s)</b>	<b>256</b>	<b>495</b>	<b>756</b>	<b>1 541</b>	<b>2 129</b>

Table 2 - Source: ODDO BHF Securities



## Sum-of-the-parts valuation

We value the company using the sum-of-the-parts method. We base our calculations on the management's priorities, namely the ZENEO Midazolam, ZENEO Hydrocortisone and ZENEO Adrenaline combinations.

We divide ZENEO Midazolam into two parts to reflect the agreement with BARDA and the epilepsy market where regional agreements have already been forged. Revenues from the BARDA contract will come from milestone payments with \$ 35m for research and development work (including the paediatric dose), and \$ 60m billed on shipment which we factor in as of 2024. Optional sales for an additional \$ 59m could follow in 2027 by our estimates.

At the same time, we model peak sales of € 187m for ZENEO Midazolam, € 98m for ZENEO Hydrocortisone and € 341m for ZENEO Adrenaline for Crossject's partners, which will subsequently pay royalties. Note that Crossject will pay 2% royalties on its sales to Sofigexi under the 2011 agreement up to a maximum of € 17m.

### Summary of our valuation model

Drug/Indication	Approval Year	Peak sales (Partners) (€ m)	NPV (€ m)	PoS	NPV adj (€ m)	NPV adj/share (€)
Midazolam (epileptic seizure)	2024e	187.44	110	90%	99	2.7
Hydrocortisone (acute adrenal insufficiency)	2025e	98.66	23	90%	21	0.6
Adrenaline (allergic shock)	2026e	341.59	116	90%	105	2.8
BARDA deal	2025e		62	100%	62	1.7
Net debt					-23	-0.6
<b>Equity value</b>						<b>7.1</b>

Table 3 - Source: ODDO BHF Securities

### NPV of ZENEO Midazolam

€ m	2024e	2025e	2026e	2027e	2028e	2029e	2030e
Sales	0.00	5.49	13.79	27.72	41.77	55.94	56.18
Sofigexi royalties (-2% up to € 17m)	0.00	-0.11	-0.28	-0.55	-0.84	-1.12	-1.12
Gross margin	86%	86%	86%	86%	90%	90%	90%
COGS	0.00	-0.77	-1.93	-3.88	-4.18	-5.59	-5.62
R&D	-4.00	-3.00	-3.00	-3.00	-3.00	-3.00	-3.00
% sales	#DIV/0!	55%	0%	0%	0%	0%	0%
SG&A	-5.00	-5.00	-5.00	-5.00	-5.00	-5.00	-4.49
% sales	30%	10%	10%	10%	10%	10%	8%
EBIT	-9	-3	4	15	29	41	42
Margin	#DIV/0!	-1	0	1	1	1	1
Tax	2	1	-1	-4	-7	-10	-10
Tax rate	25%	25%	25%	25%	25%	25%	25%
NOPAT	-7	-3	3	11	22	31	31
Change in WCR	0	-1	-1	-1	-1	-1	0
Capex	0	0	-1	-1	-2	-2	-2
FCF	-7	-3	1	10	18	27	29
WACC	13.31%						
Sum of DCF	77						
Terminal value	34						
Terminal growth rate	-40%						
NPV	110						
PoS	90%						
<b>Adjusted NPV</b>	<b>99</b>						

Table 4 - Source: ODDO BHF Securities



NPV of ZENEO Hydrocortisone							
€ m	2024e	2025e	2026e	2027e	2028e	2029e	2030e
Sales	1.9	1.9	12.90	2.51	5.05	7.93	10.84
Sofigexi royalties (-2% up to € 17m)	-0.04	-0.04	-0.26	-0.05	-0.10	-0.16	-0.22
Gross margin	60%	60%	60%	60%	60%	60%	60%
COGS	-0.74	-0.74	-5.16	-1.00	-2.02	-3.17	-4.34
R&D	-0.10	-0.05	0.00	0.00	0.00	0.00	0.00
% sales	NA	10%	0%	0%	0%	0%	0%
SG&A	-0.10	0.00	0.00	0.00	0.00	0.00	0.00
% sales	NA	0%	0%	0%	0%	0%	0%
EBIT	1	1	7	1	3	5	6
Margin	NA	NA	58%	58%	58%	58%	58%
Tax	0	0	-2	0	-1	-1	-2
Tax rate	25%	25%	25%	25%	25%	25%	25%
NOPAT	1	1	6	1	2	3	5
Change in WCR	0	0	-2	2	0	0	0
Capex	0	0	-1	0	0	0	0
FCF	0	1	3	3	2	3	4
WACC	13.31%						
Sum of DCF	17						
Terminal value	7						
Terminal growth rate	-40%						
NPV	23						
PoS	90%						
<b>Adjusted NPV</b>	<b>21</b>						

Table 5- Source: ODDO BHF Securities

NPV of ZENEO Adrenaline							
€ m	2024e	2025e	2026e	2027e	2028e	2029e	2030e
Sales	0.00	0.0	6.14	18.48	37.06	55.76	62.12
Sofigexi royalties (-2% up to € 17m)	0.00	0.00	-0.12	-0.37	-0.74	-1.12	-1.24
Gross margin	90%	90%	90%	90%	90%	90%	90%
COGS	0.00	0.00	-0.61	-1.85	-3.71	-5.58	-6.21
R&D	-2.50	-2.50	-0.25	-0.25	-0.25	-0.25	-0.25
% sales	NA	NA	4%	1%	1%	0%	0%
SG&A	-5.00	-5.00	-5.00	-5.00	-5.00	-5.58	-6.21
% sales	NA	10%	10%	10%	10%	10%	10%
EBIT	-8	-8	0	11	27	43	48
Margin	NA	NA	2%	60%	74%	78%	78%
Tax	2	2	0	-3	-7	-11	-12
Tax rate	25%	25%	25%	25%	25%	25%	25%
NOPAT	-6	-6	0	8	21	32	36
Change in WCR	0	0	-1	-2	-3	-3	-1
Capex	0	0	0	-1	-1	-2	-2
FCF	-6	-6	-1	6	16	27	33
WACC	13.31%						
Sum of DCF	78						
Terminal value	38						
Terminal growth rate	-40%						
NPV	116						
PoS	90%						
<b>Adjusted NPV</b>	<b>105</b>						

Table 6 - Source: ODDO BHF Securities





## Sum-of-the-parts valuation of Crossject (€)

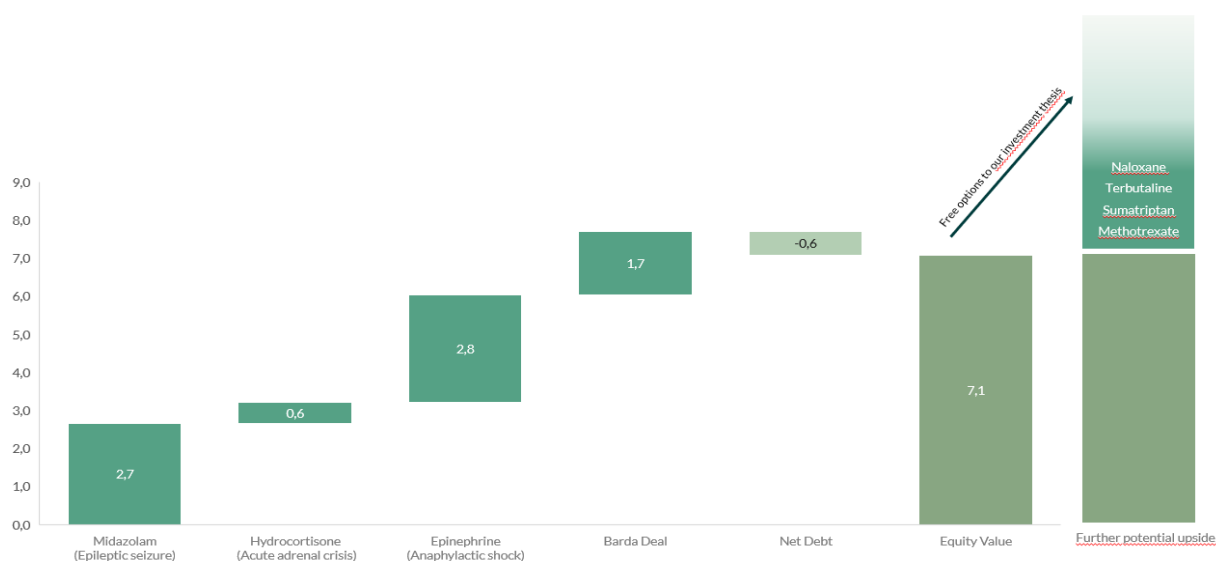


Chart 7 - Source: ODDO BHF Securities

## Current company pipeline with the company's peak sales estimates

Indication	Products	Noteworthy facts	Peak sales (€ m) (ODDO BHF estimates)	Css (according to the company) (€ m)	Priority
Anaphylactic shock	ZENEO® Adrenaline	2.3m auto-injectors sold per year in the UK 4.5m units sold per year in the US	341.0	158.0	1
Epileptic seizure	ZENEO® Midazolam	6,000 deaths/year in Europe and in the US	187.0	88.0	1
Overdose (opioids)	ZENEO® Naloxone	49,000 deaths/year in the US 97.3m patients with at least 1 opioid prescription	-	64.0	2
Severe asthma crisis	ZENEO® Terbutaline	13,000 deaths/year in Europe	-	107.0	2
Acute adrenal insufficiency	ZENEO® Hydrocortisone	No easy to use solution adapted for emergency situations	98.0	18.0	2
Migraine Cluster headaches	ZENEO® Sumatriptan	+7m sumatriptan injections/year	-	65.0	3
Polyarthritis	ZENEO® Methotrexate	Disabled patients	-	86.0	3
Parkinson's disease	ZENEO® Apomorphine	Disabled patients	-	53.0	3

Chart 8 - Sources: Crossject, ODDO BHF Securities



# ZENEO, AT THE HEART OF THE DRUG-DEVICE COMBINATION SEGMENT

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*ZENEO is a pre-filled, needle-free, single-use auto-injection system. The value added with a drug-device combination product lies in the administration system. The injectable drug market accounts for over 20% of the pharmaceuticals market, driven in part by self-injection products. We see in this innovation a real improvement in patient comfort with the assurance of an efficient injection, particularly in emergency situations.*

## A system based on French expertise

The ZENEO system is a significant technological advance. This needle-free autoinjector has successfully miniaturised technologies initially designed for the aerospace and automotive sectors that are now applied to the pharmaceuticals sector.

ZENEO's main aim is to deliver swift and precise administration of treatments through the skin and even clothing, thus offering an efficient alternative to traditional injections.

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### An autoinjector bringing together several specialties

Drawing its inspiration from technologies used in the automotive and aerospace industries, ZENEO provides an injection in two stages through a fast-acting mechanism. The gas generator is triggered through a nitrocellulose-based mixture that compresses the drug to pressures of up to 350 bars. The dose is expelled through a nozzle in contact with the skin or clothing, all in less than a tenth of a second.

The ZENEO injector is comprised of five key components:

- **A tube in pharmaceutical-quality glass:** This glass tube is siliconized and depyrogenated to ensure safety and compatibility with treatments. It can withstand up to 1,200 bars of pressure, which is essential to propel the medication.  
It is developed in partnership with SCHOTT. Crossject made the strategic decision to acquire tempered technology. This stage, which helps strengthen this component mechanically, is conducted at one of the company's manufacturing sites (Haute Savoie).
- **A nozzle:** The nozzle is polycarbonate with sub-millimetre conduits that allow the medication to be released precisely and at very high speed. This is a plastic component that can be produced by a range of plastics manufacturers specialising in pharmaceuticals applications. Crossject collaborates with MORA to manufacture them. Competition can be promoted among subcontractors to improve profitability and diminish supplier risks.
- **A gas generator:** It is based on energy-efficient materials and is responsible for propelling the medication at high speed through the nozzle, allowing for up to 1,200 bars of pressure.



- **An actuator:** All the components for the actuator are produced internally. The actuator is a sub-system that forms part of the complex components that represent a barrier to entry: pyrotechnical mechanisms for large-scale use.
- **An elastic membrane:** It is an elastomer membrane that is ultra-extendible. While manufacture of the membrane requires a more specialised approach, there are several suppliers capable of providing this (Hutchinson is currently the approved supplier).

Overview of the ZENEO injector

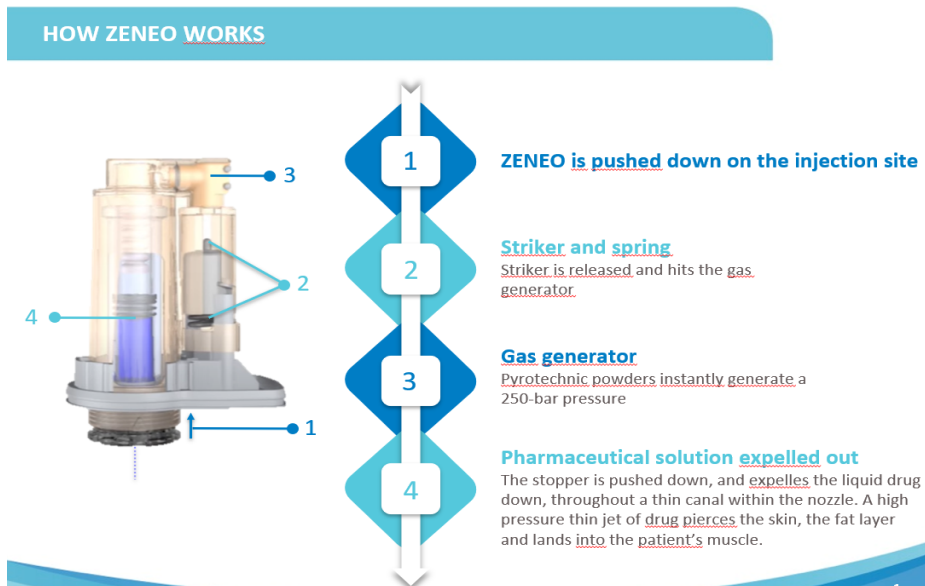


Chart 9 - source: Crossject

### What are ZENEO's advantages?

**An ergonomic system that can adapt depending on the medication to be injected**

ZENEO adapts to a range of metrics such as medication viscosity and dose quantity which can be up to 70ml. Seven clinical trials have been published by the company to assess drug injection quantities based on content. It is worth noting that the blood concentration curves for products after using ZENEO or traditional injection, overlap irrespective of the size or fragility of the molecules. We can thus conclude that the desired quantity is assured of being injected. Injection of 100% of the product is virtually instantaneous (administration in less than 50ms with no product loss).

Crossject's device includes three models based on the depth of the injection: intradermic, subcutaneous and intramuscular (the three priority products are in IM). These characteristics make ZENEO a flexible tool that can be adapted to varying formulations of medication to meet patients' specific needs. Specifically, ZENEO has been used successfully in intramuscular injection, even through clothing, for emergency situations such as epileptic seizures, thereby establishing an exceptional standard in drug administration.



## Guarantee of efficiency even in stress situations

The fact that the medication is already pre-filled in the injector means its use is particularly efficient in emergency situations such as epileptic seizures and allergic reactions. No upstream handling is required, be it in terms of the dose or reconditioning. The combination is ready to use, even for intramuscular injections and potentially through clothing. This advantage looks particularly key in terms of the mechanism's growing use, with the US government convinced to stockpile ZENEO Midazolam devices for the population in the event of a chemical attack.

Moreover, according to Crossject, it is estimated around 10% of the population has a fear of needles and up to 30% are not comfortable with auto-injections involving needles. This psychological barrier could be overcome by ZENEO which provides patients with a reliable and secure auto-injection solution. According to data published, the discomfort caused by ZENEO is seen as negligible for less than a tenth of a second. The injection is quick and conducted into two intuitive stages; firstly, the green part is twisted to remove the cap, after which users position ZENEO and then press to inject. This avoids the risk of needle-based injury and infection of the person administering and the patient.

ZENEO thus ensures comfort and safety and better patient observance.

## Swift development

While this is a drug-device combination product, regulatory concerns revolve mainly around the administration route and a demonstration of efficiency in line with the standard of care for the condition. Indeed, injected products like Midazolam are already approved and require no further efficacy tests.

As with generic treatments, a so-called bioequivalence trial is conducted mainly to confirm that the dose administered under ZENEO is identical (comparable total injected dose and blood concentrations) to that with a conventional injection. The aim here is to ensure that the drug concentration equates to between 80% and 125% of that of the comparator.

Moreover, the regulatory expectations in Europe are very close to those seen in the US, which is an advantage in its development plan.

Indeed, five standards are required to obtain market authorisation:

- **Product formulation.** This aspect can be seen as a formality given that Crossject's strategy currently is to target generic products.
- **Stability of the medication within the ZENEO system.** While tests must be conducted over a period of 24 months, registration can be filed ahead of the final results (after an initial period of six months).
- **Drug sterility test.** This test is conducted on the 'fill and finish' line and not by product.
- **Bioequivalence trial.** This constitutes the required clinical test. This test can take from two to three months, between the first injection for the first volunteer and the last injection for the final one.



- **Utilisation study.** Given that the product is designed also for use by non-professionals (patients, acquaintances, passers-by, etc.), authorities require tests to simulate use by target users in order to ensure the device is used correctly.

**Unlike the development of a traditional pharmaceutical compound, we believe that the probability of clinical and then regulatory success is much higher for the development of a combination with ZENEO. The risks stem more from patients converting to the medical device, the target market and large-scale production.**

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## Unique and protected technology

ZENEO has over 500 patents to its name around the world protecting the device up until 2038.

These patents cover the optimisation of ZENEO in the framework of its industrialisation (mechanical aspects, waterproofing, triggering mechanisms, etc.) and allow the robustness of the device to be enhanced as well as reducing manufacturing costs. To date, the intellectual property rights are fully secured, and no patent is currently the focus of opposition proceedings.

Moreover, the ZENEO+drug combination will be filed as a treatment in its own right. Crossject has also patented innovative formulations for Adrenaline (filed in 2018) and hydrocortisone (filed in 2020).

However, we think the main protection comes from the ZENEO's industrial production. Crossject has two technologies used in the manufacturing process for ZENEO, namely heat-tempered glass and gas generator production.

**In conclusion, ZENEO marks a significant step forward in drug administration, offering speed, precision and adaptability. The only other needle-free device on the market has been developed by Zogenix for acute migraines (administration of sumatriptan). Unlike ZENEO, the medical device for Zogenix has rigid technology which involves redeveloping the whole of the product for each drug.**

## Industrial aspect the biggest challenge in our view

**Development time and costs are thus reduced in comparison with a conventional pharmaceutical development, the clinical and regulatory risks are limited and profitability is attractive on paper. This aspect will come into play if, and only if, Crossject achieves its production targets.**

This is where the biggest challenge lies, in our view, and allocated costs need to be aligned to the sales ambitions and the partnerships signed.

In 2020, Crossject undertook a major shift, as it transitioned from a company with an R&D focus to an industrial operation with production capacity. In 2021, the company continued to strengthen its industrial operations, placing the emphasis on quality. Thanks to a control programme comprising over 2,500 tests, Crossject has successfully guaranteed an injection reliability rate of 99.999% for ZENEO. It is important to underline this ratio here, as it represents guidance from the FDA that is set to become mandatory quite soon (it was mandatory for the BARDA tender). For any application to file a drug with the regulatory authorities, companies need to demonstrate products' reproducibility of quality and stability over the long term (the targeted expiries range from two to three years), before undertaking clinical demonstration.



To date, Crossject has production capacity of 500k ZENEO units p.a., extendible to over 6m units p.a. from 2028 (two plants close to Dijon). The French group also works with several subcontractors which will also have to keep up the pace. In this context, Crossject has strengthened its collaboration with Cenexi, which provides the filling and final assembly of ZENEO autoinjectors at its site in Belgium. More specifically, aside from its internal production, Crossject has the capacity to produce 250k devices with external partners (in the process of being doubled to 500k). Efforts to accelerate internal production are on track with an extension and the automation of the Gray site (pyrotechnical powder) which is expected to ramp up to close to 2m devices in short order. Over the last few years, Crossject has obtained pharmaceutical establishment status and obtained the certificate for best practice manufacturing (a pre-requisite with the BARDA).

Industrial process

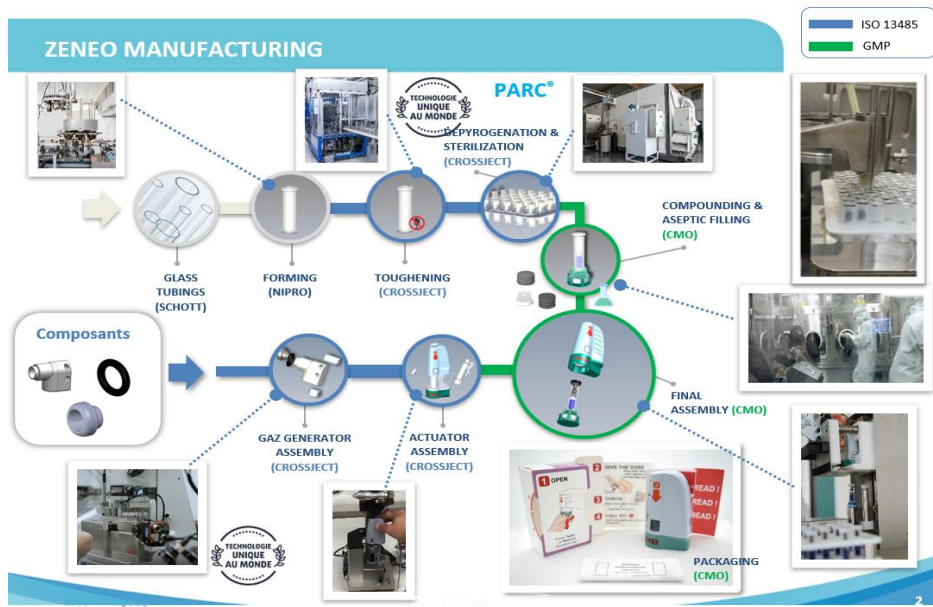


Chart 10 - Source: Crossject



# ZENEO MIDAZOLAM SPEARHEADING CROSSJECT'S PIPELINE

ZENEO Midazolam is the most advanced compound in Crossject's pipeline. The agreement forged with BARDA to develop and supply its autoinjector with midazolam plays an important role in the company's investment case, bearing in mind that this agreement: 1/ confirms the potential and appeal of the technology developed by the group, 2/ partly derisks the development of its pipeline, and 3/ signals the company's transition to the commercial phase with the recognition of its first recurrent revenues.

## Epilepsy: a mature market but where urgency is key

Crossject develops ZENEO midazolam in the treatment of epilepsy, a neurological disease characterised by the spontaneous recurrence of seizures resulting from the abnormal and simultaneous discharge of thousands of neurones into the brain. Close to 50 million people are affected by epilepsy worldwide.

### Still a growth market despite the impact of generics

The epilepsy market (all types taken together) is currently estimated at \$ 6.1bn and is expected to grow at a rate of 3.8% on average to exceed \$ 7bn in 2028 (source: Evaluate Pharma).

#### Sales projections for epilepsy market

Product Indication Sales | Top 10 Products

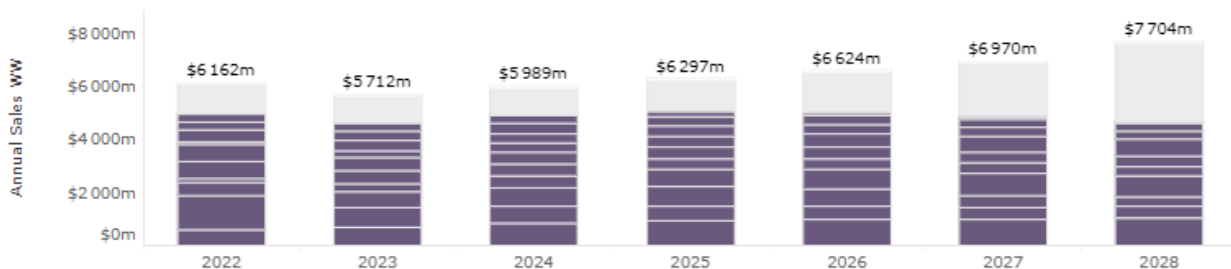


Chart 11 - Source: Evaluate

There has been reduction in the size of the market in the short term with the advent of generics of Vimpat (UCB's blockbuster treatment - \$ 1.1bn of sales in 2022).



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## Continuing medical need

Currently, the treatment of epilepsy primarily targets its symptoms, i.e. stopping the seizures or lessening their frequency and severity. Existing medical treatments help control around 70% of epileptic disorders. But for 30% of patients, the seizures remain despite the implementation of suitable therapies.

The medical need is especially pronounced given the complications and effects resulting from the episodes. One of the most severe complications is status epilepticus. This can result in permanent neurological damage and in some cases lead to life-threatening conditions. Immediate and efficient care is vital.

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## Midazolam: a profile suited to emergency treatment

Midazolam is part of the family of benzodiazepines, a class of drug that is among the main therapies used to treat epilepsy. It acts on the brain by binding to GABA-A receptors and by strengthening the effect of the inhibitory cell signalling transmitter GABA. The brain cells thus become less excitable, which ends the episode.

Midazolam is highly liposoluble, allowing it to cross the blood-brain barrier and produce therapeutic effects quickly. But the drug has a short half-life and an adverse risk profile in the long term. This limits its use to emergency treatments and particularly status epilepticus. It thus presents an ideal candidate for Crossject.

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## Status epilepticus as target market

Status epilepticus represents a major medical emergency associated with a high degree of mortality and morbidity. The outcome of status epilepticus mainly hinges on its underlying cause, but other factors (state of consciousness, age, etc.) and particularly the point of the initial treatment are factored into patient prognosis. The latter is decisive as it is the only factor over which the treating person has an influence.

Benzodiazepines are the standard of care class of therapies used to treat status epilepticus.

One intravenous injection of a benzodiazepine therapy is the treatment of choice for status epilepticus, with the episode stopped within less than five minutes of injection.





Overview of status epilepticus treatment with benzodiazepines





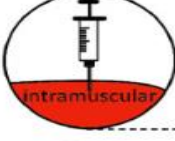


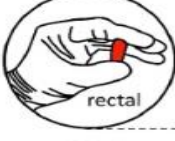



Route of delivery	Available benzodiazepines*	Time till cessation	Comment on clinical use in status epilepticus
 intra venous	<ul style="list-style-type: none"> <li>• Clonazepam</li> <li>• Diazepam</li> <li>• Lorazepam</li> <li>• Midazolam</li> </ul>	 5 min	<ul style="list-style-type: none"> <li>• Gold standard if PVC established</li> <li>• Restricted to medical professionals</li> </ul>
 nasal	<ul style="list-style-type: none"> <li>• Diazepam</li> <li>• Lorazepam</li> <li>• Midazolam</li> </ul>	 5-15 min	<ul style="list-style-type: none"> <li>• Feasible option if PVC is not yet established</li> <li>• Easy to use for medical non-professionals</li> </ul>
 intramuscular	<ul style="list-style-type: none"> <li>• Diazepam</li> <li>• Lorazepam</li> <li>• Midazolam</li> </ul>	 5-45 min	<ul style="list-style-type: none"> <li>• Feasible option if PVC is not yet established</li> <li>• Autoinjectors available for non-professionals</li> </ul>
 buccal	<ul style="list-style-type: none"> <li>• Lorazepam</li> <li>• Midazolam</li> </ul>	>30 min clock icon" data-bbox="608 354 718 416"/> >30 min	<ul style="list-style-type: none"> <li>• Feasible option for seizure clusters or in palliative care settings</li> <li>• Easy to use for medical non-professionals</li> </ul>
 rectal	<ul style="list-style-type: none"> <li>• Diazepam</li> </ul>	 >45 min	<ul style="list-style-type: none"> <li>• Feasible option for seizure clusters or in palliative care settings</li> <li>• Difficult to handle, may cause discomfort</li> </ul>
 oral	<ul style="list-style-type: none"> <li>• Clonazepam</li> <li>• Diazepam</li> <li>• Lorazepam</li> <li>• Midazolam</li> </ul>	 >60 min	<ul style="list-style-type: none"> <li>• Inadequate route for treatment of status epilepticus</li> </ul>

Chart 12 - Source: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9477921/>

Based on an assessment of the various treatment options for status epilepticus, we think the solution developed by Crossject has best-in-class potential as it offers 1/ the advantage of being usable quickly wherever the episode occurs (infeasible for intravenous and rectal formulations), 2/ a more comfortable administration method (vs IV, rectal and oral delivery) and 3/ a faster therapeutic response (vs rectal and oral administration).

We note that the nasal spray formulation and particularly UCB's Nayzilam may be regarded as a direct rival to ZENEO midazolam. But authorisation in paediatric cases would be favourable to Crossject's product given that no nasal antiepileptic is currently approved in this population. We currently forecast a price in line with Nayzilam, of \$ 311 per administered dose. This differs significantly with the price negotiated by BARDA which works out at around \$ 154 a dose.

The group's strategy of taking up position in emergency therapies looks smart at this stage, bearing in mind that: 1/ this is a market where benzodiazepines, to which midazolam belongs, are the standard of care and face little competition from other product families, 2/ midazolam's safety profile is better suited to the treatment's one-off use and 3/ emergency use treatments are secured better access to insurers' repayment plans.



## A structural agreement with BARDA

In June 2021, Crossject won a tender launched by the US government via BARDA (Biomedical Advanced Research and Development Authority) to supply, subject to the securing of marketing authorisation from the FDA, ZENEO Midazolam in the treatment of epileptic seizures for a contract worth up to \$ 155m. We expect approval to be secured by the end of the year/early 2024 in emergency use with the first orders launched in Q2 2024.

### An opportunity for initial commercial revenues

In June 2021, the group announced the conclusion of an agreement to supply its ZENEO midazolam autoinjectors to the US agency BARDA, an entity belonging to the US Department of Health and Human Services (HHS) charged with the development and management of medical countermeasures mainly in connection with bioterrorism, Opandemics and emerging diseases.

In concrete terms, the agreement with BARDA is in three parts:

- A firm order for \$ 60m to supply, subject to obtaining emergency use authorisation from the FDA, of 360,000 doses of ZENEO Midazolam, to be delivered before 2027.
- A subsidy from BARDA of up to \$ 32m to help Crossject finance the R&D and regulatory stages, allowing for launch in the US market.
- An option to buy additional autoinjectors for \$ 59m, bringing the total number of batches ordered to 776,000 units.

### Agreement in the framework of the US plan to implement medical countermeasures in public health emergencies

In the context of the actions undertaken by BARDA in its role to prepare for emergency situations involving chemical attacks, the US agency can draw on financing from the BioShield Act to collaborate with Crossject to develop and supply ZENEO Midazolam autoinjectors to treat exposure to neurotoxins. These will be part of the CHEMPACK programme and replace the diazepam doses stockpiled up to now (out-of-date stock).

The CHEMPACK programme embraces global capability to store and distribute medical countermeasures to quickly treat large numbers of people following an incident involving neurotoxic agents that impair the nervous system, leading to convulsions, respiratory failure, coma and potentially death.

Within this framework, containers of antidotes are positioned in secure locations across the United States. Since 2004, with BioShield Act authorisation and financing, there has been an acceleration in the research, development, acquisition and availability of medical countermeasures against chemical, biological, radiological and nuclear (CBRN) threats. In 2018, BARDA supported the development and approval of Seizalam (vials of midazolam for intramuscular injection); the product was approved by the FDA to treat epileptic seizures in adults, including episodes resulting from exposure to neurotoxic agents.

Given that midazolam is already approved by the FDA and that it is a more efficient treatment than diazepam, the acquisition and approval of autoinjectors of midazolam for children and adults should meet this requirement.



To this end, BARDA will provide funds to conduct the research and clinical development with a view to obtaining full regulatory approval for ZENEO Midazolam autoinjectors (as a drug-device combination product). The supply of ZENEO Midazolam autoinjectors will start once the product has received emergency use authorisation (EUA) from the FDA. Crossject must, in the context of the subsidy for R&D and regulatory development for this contract, obtain full approval from the FDA for adult and paediatric populations. In addition to the development of ZENEO Midazolam for adult populations, the agreement also includes the development of a paediatric dose.

## Initial sales from 2024

As we said earlier, the initial batch of autoinjectors will be delivered once the FDA has given its emergency use authorisation. We expect a positive opinion from the US agency at end-2023 (if there are further requests, approval could be in H1 2024), with initial deliveries in 2024.

Our model of the revenues derived from this agreement is based on the following assumptions:

- A two-stage delivery of the 360,000 doses in 2024 and 2025, based on Crossject's existing capacity.
- A second delivery in 2027 of 416,000 doses to finalise the strategic stockpile of 776,000 doses for BARDA.
- A price of \$ 154 per dose (corresponding to the payment of \$ 120m for 776,000 doses).
- Potential further deliveries to replace doses that expire (life span of three years for each dose).

## Timetable for delivering ZENEO Midazolam to BARDA including reimbursement of R&D and regulatory advances

€ m	2023e	2024e	2025e	2026e	2027e	2028e
Sales	0.0	37.2	37.2	0.0	27.9	27.9

Table 13 - Source: ODDO BHF Securities

## Peak sales of € 187m for ZENEO Midazolam in 2034

The epilepsy market is significant due to the number of cases and in value terms, despite the entry of many generics. There are 50m people with epilepsy worldwide and sadly 6,000 deaths per year in Europe alone.

We think that the intra-muscular administration of ZENEO Midazolam is an advantage, as is the ease of use for the patient of a third party, notably in the case of children. Administration is therefore straightforward with the patient experiencing no lesions, even during a seizure.

We retain the US and Europe as the main target markets. At this stage, we are not modelling revenues from other regions like those related to the recent deal signed with AFT Pharmaceuticals for the distribution of ZENEO Midazolam in Australia and New Zealand, which we see as a wildcard option in our investment case.



We model the size of Crossject's target market at \$ 1,500m in the US and € 500m in Europe. We remain conservative on the expected utilisation rate and market share gained. As for all developments, we imagine that Crossject will find a regional partner on mature markets. The trend in market share is fully linked to commercial partners. As such, we currently model a market share peak at 10% and royalties of 30% for Crossject, noting that the company will be responsible for developing and registering the combination.

The other adjustment variable is naturally the price. We retain pricing equal to the catalogue price of UCB's Nayzilam. This nasal spray is sold at \$ 622 per box (containing two devices) in the US. We are not applying an additional premium, although one could be considered. That said, we model a price below 40% in Europe.

All told, our assumptions give peak sales of € 187m in 2034 for Crossject's future partner and royalties at € 57m out to this horizon for Crossject. This sales target requires production of 750k devices out to this horizon.

Sales of ZENEO Midazolam					
€ m	2023e	2024e	2025e	2026e	2027e
<b>North America</b>					
NA Population (M)	379	382	384	387	389
Epilepsy prevalence in the NA	1.20%	1.20%	1.20%	1.20%	1.20%
Numbers of patients (m)	5	5	5	5	5
Annual cost (Assuming 1 dose /year on average)	311	311	311	311	311
Total US Market exp	1 414	1 424	1 433	1 443	1 452
% Penetration (Crossject)	0%	0%	1%	3%	5%
<b>Sales by partner (\$ m)</b>	-	-	<b>14</b>	<b>36</b>	<b>73</b>
Volume ZENEO (000)			46	116	233
Royalties	30%	30%	30%	30%	30%
Royalties (\$ m)	-	-	4	11	22
Royalties	-	-	4	10	20
<b>EU-5</b>					
France	69	69	69	70	70
Germany	79	79	79	78	78
Italy	61	61	61	61	61
Spain	47	47	47	47	47
United Kingdom	67	68	68	68	69
EU-5 Population (m)	324	324	324	325	325
Epilepsy prevalence in Europe	0.82%	0.82%	0.82%	0.82%	0.82%
Number of Epilepsy patients	3	3	3	3	3
Annual cost / patient (Assuming 2 doses / patient on average)	187	187	187	187	187
Total Eu market in Meur	495	496	496	497	497
% Penetration (Crossject)	0%	0%	1%	3%	5%
<b>Sales by partner</b>	-	-	<b>5</b>	<b>12</b>	<b>25</b>
Volume ZENEO (000)			27	67	133
Royalties	30%	30%	30%	30%	30%
Royalties	-	-	1	4	7
<b>Total sales by partner</b>	-	-	<b>18</b>	<b>45</b>	<b>91</b>
<b>Corssject Revenue (Royalties)</b>	-	-	<b>5</b>	<b>14</b>	<b>28</b>
<b>Total Volume to provide (000)</b>			<b>73</b>	<b>183</b>	<b>367</b>

Table 14 - Source: ODDO BHF Securities



# ZENEO HYDROCORTISONE IN ACUTE ADRENAL INSUFFICIENCY (AAI)

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*Based on the same technology, ZENEO Hydrocortisone is being developed to treat adrenal crisis and is the second priority component in Crossject's pipeline. We see strong clinical interest among renowned players due to: 1/ an unmet medical need in acute adrenal insufficiency (AAI) treatment due to the complexity of solutions currently on the market; 2/ a price premium that can be envisaged due to the urgent nature of ZENEO Hydrocortisone, as well as; 3/ the deal signed with Eton for the commercialisation of this product. We anticipate a commercial launch in 2025 and model peak sales for the product at €98 million.*

## An unmet medical need, for limited prevalence

Adrenal insufficiency (AI) is a rare condition resulting from corticosteroid deficiency, whether primary (primitive, peripheral) or secondary (constrictropic, central). Prevalence is estimated at roughly 5 cases per 10,000 people in the US and Europe. In 7% of cases, it manifests as AAI, the most serious form of AI. The main symptoms include hypotension, psychological effects, abdominal pain, nausea, vomiting and fever. A patient's condition can change rapidly, with a mortality rate of 0.5 cases per 100 patients each year. Although the disease has been well studied, it is often difficult to diagnose which can cause delays in treatment and higher morbidity and mortality rates. This means that early detection and immediate intervention are crucial to saving patients' lives.

### Hydrocortisone as standard of care for the disease

At this time, the most commonly used therapy is hydrocortisone 100mg administered intravenously or intramuscularly with a needle, commercialised by Pfizer under the name Solu-Cortef. However, the process to inject the drug is complex and time-consuming. The user needs an emergency injection kit containing a vial, alcohol wipes, a sterile syringe with a needle, etc. In general, patients and their families spend half a day receiving injection training at the hospital. The preparation of the injection involves a dozen stages, such as mixing the powder in the vial and extracting the solution using a syringe, etc. **There is thus an unmet need on the market for an easy-to-use form of hydrocortisone to treat adrenal crisis.**



### Treatment guidelines for AAI

	Stress Dosing [5][27][56]	Fluid Resuscitation [5][27]
ADULTS	100 mg hydrocortisone IV/IM followed by 200 mg over the next 24 hours given IM/IV (50 mg every 6 hours) or as a continuous infusion	1 liter of normal saline or 5% dextrose in 1 liter of normal saline in case of hypoglycemia followed by maintenance fluids
CHILDREN	Hydrocortisone dose is calculated as 50-100 mg per meter square followed by 50-100 mg per meter square over the next 24 hours given IM/IV (divided into doses given every 6 hours) or as a continuous infusion	Normal saline bolus at a dose of 20 ml per kilogram of body weight, with repeated doses at up to 60 ml per kilogram the first hour. Add dextrose at a dose of 0.5 to 1 g per kilogram in case of hypoglycemia

Table 15 – Sources: Adrenal Crisis by Ghada Elshimy; Venu Chippa; Jordan M. Jeong.

### Pfizer is the main player with its Solu-Cortef kit

The ISA market is currently dominated by Pfizer’s Solu-Cortef, at a price of around \$ 25 for 100mg of injectable powder. Sales exceed \$ 85m per year according to data from IQVIA.

### Emergency injection kit: Solu-Cortef



Chart 16 – Source: Pfizer, Memorial Sloan Kettering Cancer Center

The other direct competitor that we have identified is ATRS-1902 in the form of an auto-injector developed by Antares Pharma, a US biotech specialising in self-administered injectables. The company was acquired by last year for a total of € 960m. ATRS-1902 is a liquid stable formulation of hydrocortisone (100mg) contained in a rescue pen, which simplifies administration into two stages. The company was granted Fast Track designation by the FDA in January 2022 for this candidate drug following the positive results for phase I evaluating the pharmacokinetic profile for ATRS-1902 compared to that of Solu-Cortef in 32 healthy adults. However, for the time being we have no update on the programme’s progress.

## ZENEO Hydrocortisone, an optimal solution for AAI

The ZENEO technology developed by Crossject enables rapid and efficient intramuscular injection without a needle in an emergency during an adrenal crisis. It is in the form of a two-step, ready-to-use kit. No professional training is needed for the injection thanks to the simplicity of its administration, meaning that non-health professionals can use it.



We think that the Crossject solution stands out from the formulations already on the market due to its simplicity (use in 2 steps vs 12 steps) and rapid administration (less than a tenth of a second vs 20 minutes) which holds a major competitive advantage, in particular in situations where quick intervention is crucial for the survival of a patient with AAI. In parallel, a pricing premium could certainly be envisaged due to the emergency nature of ZENEO Hydrocortisone.

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## A partnership with Eton for North America

On the North American market (US and Canada), Crossject has signed an agreement to commercialise ZENEO Hydrocortisone with the company Eton Pharmaceuticals. Listed on the NASDAQ with market capitalisation of \$ 100m, Eton specialises in rare diseases and currently has three drugs already commercialised: Alkindi Sprinkle (hydrocortisone in granules), Carglumic Acid for the treatment of hyperammonemia and Betaine Anhydrous in homocystinuria. We can therefore immediately see portfolio synergies with its drug in granules for the chronic treatment of paediatric forms.

The agreement states that Eton will be responsible for all regulatory and commercial activities. Crossject will take charge of carrying out, at its own cost, the development, clinical and manufacturing activities. Of the \$ 5m in milestones signed in 2021, some \$ 4m is still to be paid. Crossject will then receive a payment of a supply price for each ZENEO Hydrocortisone sold to Eton, which we estimate at € 50, and 10% of royalties, followed by \$ 6m paid depending on the commercial milestones triggered by 3 annual net sales thresholds at Eton.

Crossject plans to launch a bioequivalence study in 2024, for which the full process is expected to take 6 months. We predict a request for the product's registration at end-2024, which could result in FDA approval in 2025.

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## Peak sales at € 98m

Like for other developments on the market, we are focused on the western markets, namely Europe and the US. On the North American market (US and Canada), Crossject has already signed an agreement to develop ZENEO Hydrocortisone with the company Eton Pharmaceuticals. The agreement states that Eton will be responsible for all regulatory and commercial activities.

As it stands, patients suffering from adrenal crises tend to use Solu-Cortef. The market for Solu-Cortef currently exceeds \$ 85m per year, according to data from IQVIA. We think that patients are likely to prefer a simple and intuitive self-injection. In our view, the target population is patients suffering from adrenal insufficiency and we estimate a penetration rate of up to 50%. We predict a request for the product's registration in H2 2024, which could result in FDA approval in 2025.

Due to its emergency nature, Crossject hopes that the price range in the US will come to \$ 500-1,000. Factoring in the company's estimates, we apply a price of \$ 750 for the US and a level 40% lower in Europe. The sales potential comes to € 98m on our estimates.





Sales estimates for ZENEO Hydrocortisone										
€ m	2023e	2024e	2025e	2026e	2027e	2028e	2029e	2030e	2031e	2032e
<b>North America</b>										
NA Population (M)	379	382	384	387	389	392	394	396	398	400
Adrenal insufficiency prevalence in the NA	0,05%	0,05%	0,05%	0,05%	0,05%	0,05%	0,05%	0,05%	0,05%	0,05%
Adrenal insufficiency prevalence (patient)	0,178	0,179	0,181	0,182	0,183	0,184	0,185	0,186	0,187	0,188
Price / dose (\$)	750	750	750	750	750	750	750	750	750	750
Total market in the US (\$m)	133,55	134,48	135,40	136,29	137,16	138,01	138,84	139,64	140,42	98,52
% Penetration (Crossject)	0%	0%	2%	5%	10%	20%	30%	40%	50%	50%
<b>Sales by partner (\$ m)</b>	-	-	3	7	14	28	42	56	70	71
Volume ZENEO (000)			4	9	18	37	56	74	94	94
Royalties	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Royalties (\$ m)	-	-	0	1	1	3	4	6	7	7
\$/€	0,93									
Royalties	-	-	0	1	1	3	4	5	7	7
Milestones from ETON		2	2							50%
<b>EU-5</b>										
France	68.78	69.053	69.316	69.569	69.813	70.04	70.252	70.453	70.645	70.832
Germany	79.059	78.801	78.533	78.266	77.996	77.725	77.451	77.172	76.892	76.597
Italy	61.402	61.379	61.349	61.32	61.283	61.24	61.192	61.14	61.083	61.022
Spain	47.1	47.136	47.161	47.189	47.209	47.223	47.235	47.248	47.257	47.264
United Kingdom	67.466	67.763	68.052	68.335	68.604	68.858	69.102	69.338	69.563	69.784
EU-5 Population (M)	324	324	324	325	325	325	325	325	325	325
Adrenal insufficiency prevalence in the NA	0,05%	0,05%	0,05%	0,05%	0,05%	0,05%	0,05%	0,05%	0,05%	0,01%
Adrenal insufficiency prevalence (patient)	0,15	0,15	0,15	0,15	0,15	0,15	0,15	0,15	0,15	0,15
Price / dose (\$)	419	419	419	419	419	419	419	419	419	419
Total market in Europe	64	64	64	64	64	64	64	64	64	64
% Penetration (Crossject)	0%	0%	0%	2%	5%	10%	20%	30%	40%	50%
<b>Sales by partner</b>	-	-	-	1	3	6	13	19	26	32
Volume ZENEO (000)				3	8	15	31	46	61	76
Royalties	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
Royalties	-	-	-	0	0	1	1	2	3	3
<b>Total sales by partner</b>	-	-	0,0	7,6	16,0	32,1	51,5	71,1	90,9	97,7
<b>Crossject Revenue (Royalties)</b>	-	1,9	1,9	0,8	1,6	3,2	5,2	7,1	9,1	9,8
<b>Total Volume to provide (000)</b>	-	-	4	12	26	52	86	120	155	171

Table 17 - Source: ODDO BHF Securities





# ZENEO ADRENALINE AS A FIRST-LINE TREATMENT FOR ANAPHYLAXIS

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*ZENEO Adrenaline is a needle-free, single-use injection to treat anaphylactic shock. It is being developed by Crossject and we consider it to be the most promising asset from a commercial standpoint (commercial launch in 2026 in our estimates), with a sales peak of € 380m worldwide for its future partner.*

## A growing but competitive market

Anaphylactic shock is the most dangerous form of the allergy and can result in death. Anaphylaxis can be triggered when the immune system has an excessive reaction to an allergen.

In France, allergies affect between 25% and 30% of the population, with close to 5% being cases of anaphylaxis. Anaphylactic shock requires emergency medical intervention. According to the recommendations of specialist institutions, adrenaline via intramuscular injection is the only first-line treatment in this case.

Epinephrine auto-injectors are the standard of care for the indication with a market estimated at \$ 2bn in 2022 and which should grow at an average pace of 4.9% to reach \$ 3.2bn in 2032 (Evaluate Pharma).

The market for adrenaline auto-injectors has many players. We note in particular the oldest Viatrix EpiPen, as well as Auvi-Q and Allerject from Kaleo, Emerade Adrenaline, Twinject, Adrenaclick, Jext, and so on (see chart hereafter). Bear in mind that beyond auto-injectors, other forms of administration are being developed, such as Anaphylm (a film placed under the tongue in the event of anaphylaxis and Neffy (an adrenaline nasal spray).



Sales forecasts for adrenaline auto-injectors

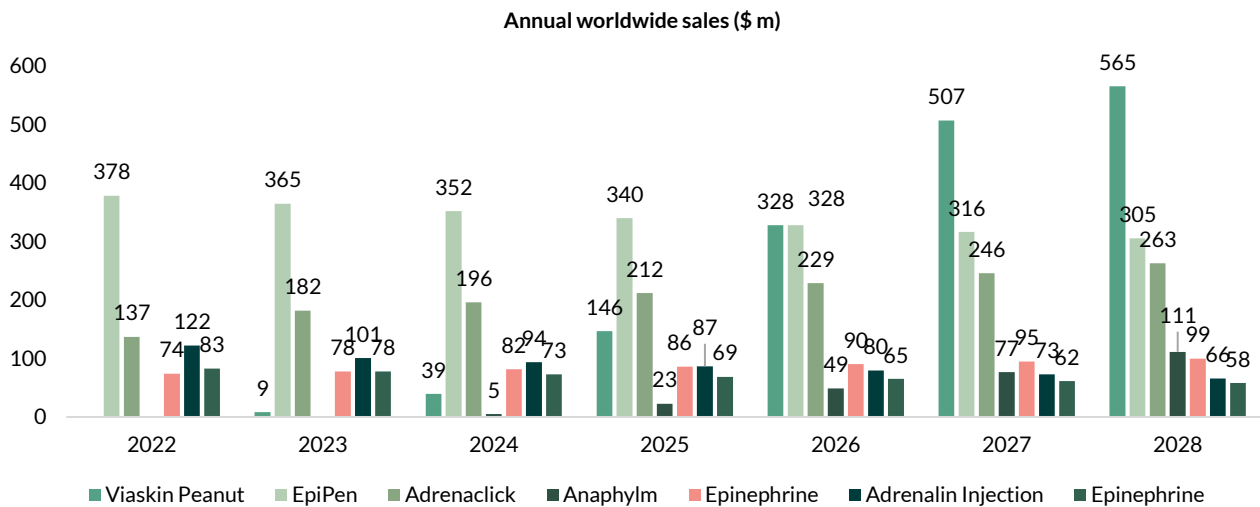


Chart 18 – Source: Evaluate Pharma

## ZENEO Adrenaline: an advantageous position

### The lifecycle is potentially twice as long

The formulation of ZENEO Adrenaline eliminates allergen components (sulphites), unlike products present on the market. This means that the treatment has better conservation performances and duration of stability than its market competitors. Indeed, the average lifecycle of the other adrenaline auto-injectors is 24 months. With a target lifecycle of up to 2-3 years, we think that ZENEO Adrenaline has a major competitive advantage in terms of the formulation.

In a study carried out in Canada on the expired EpiPen, researchers found that the dose of adrenaline can lose up to 30% of the original dose 5-7 years after the original expiration date. Note that the dose of adrenaline recommended by the authorities for the treatment of anaphylactic shock is 0.01mg/kg for children and adults. Moreover, the FDA’s current position is to avoid using expired drugs.

### An adaptable dosage

Adrenaline auto-injectors are often commercialised in two doses, in a format of 0.15mg for children (15-30kg) and 0.30mg for adults (> 30kg).

However, Auvi-Q is available in a lower dosage of 0.1mg for the paediatric population (>15kg) and Emerade is the only injector to offer the option of 0.5mg of adrenaline (adult > 60kg).



We think that Crossject stands out from the existing offering thanks to: 1/ flexibility provided by the ZENEO solution enabling a greater variety of dosages to better meet the needs of patients of different ages; 2/ better dosage control: the dose of the drug is fully injected and leaves no residue in the injector (unlike existing products).

## User-friendliness in an emergency

In terms of ease of administration, we believe that Auvi-Q is ZENEO's most serious competitor. Auvi-Q is an epinephrine auto-injector produced by Kaléo and authorized on the market in 2012.

### Auvi-Q auto-injector from Kaléo



Chart 19 - Source: Kaléo

Studies comparing the ergonomics of Auvi Q with the EpiPen SoC have shown that users prefer the size and shape of the Kaleo auto-injector. The Kaleo auto-injector does not dispense with the need for a needle, which inevitably implies a certain failure rate in emergency procedures. Crossject's device therefore has a very clear competitive advantage.

Alternatives to needles, such as Neffy and Anaphylm, are certainly more compact and easier to use, but their development still raises questions, as in the case of the FDA's CRL for Neffy, in which the agency demanded additional tests on the grounds that this drug has not been evaluated in real-life conditions of anaphylactic shock and is not bioequivalent to EpiPen.

The problem is that, despite all the aids around auto-injectors (visual or auditory), it is impossible to guarantee 100% correct handling by the patient, given that the injection often takes place in a situation of heightened stress.

Crossject's ZENEO technology enables its auto-injector to be well positioned in the adrenaline market in terms of both flexibility of use and ergonomics. We think that the main challenge remains regulatory and industrial issues, with a view to commercial launch in 2026. The possibility of a new partnership in this area cannot be ruled out, in our view.

## Peak sales of € 341m for ZENEO Adrenaline

ZENEO Adrenaline combination is the most commercially promising candidate for Crossject, in our view. Now that the formulation has been modified to no longer contain sulphites, Crossject should be able to submit its application for US marketing authorisation during 2025. In the meantime, we believe that the company will have to repeat a bioequivalence trial with its formulation. Initially, Crossject had signed a commercial partner in 2013, but managed to reacquire them in 2020. This agreement will result in Crossject paying royalties based on a single-digit percentage of product sales (assumed to be 8%).



We consider that the ZENEO-Adrenaline combination could have a price premium over EpiPen (currently \$ 650 for two syringes). As mentioned above, Crossject currently has no partners in the two main regions of the world, and a deal could therefore be struck in the short term. Developing market share will continue to depend on its partner's expertise in marketing emergency solutions.

ZENEO Adrenaline estimates								
Adrenaline (allergic shock)	2023e	2024e	2025e	2026e	2027e	2028e	2029e	2030e
<b>North America</b>								
US population (m)	340	343	345	347	350	352	354	356
Canada Population	38	39	39	39	40	40	40	40
NA Population (m)	379	382	384	387	389	392	394	396
Prevalence in NA	1%	1%	1%	1%	1%	1%	1%	1%
Prevalence (patient)	4	4	4	4	4	4	4	4
Price / dose (\$)	390	390	390	390	390	390	390	390
Total US Market exp.	1 515	1 525	1 535	1 546	1 555	1 565	1 574	1 584
Penetration (Crossject)	0%	0%	0%	1%	3%	6%	9%	10%
Sales by partner (\$ m)	-	-	-	15	47	94	142	158
Volume ZENEO (000)	-	-	-	40	120	241	363	406
Royalties	20%	20%	20%	20%	20%	20%	20%	20%
Royalties (\$)	-	-	-	3	9	19	28	32
\$/ €	0.93							
<b>Royalties</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>3</b>	<b>9</b>	<b>17</b>	<b>26</b>	<b>29</b>
<b>EU-5</b>								
France	68.78	69.053	69.316	69.569	69.813	70.04	70.252	70.453
Germany	79.059	78.801	78.533	78.266	77.996	77.725	77.451	77.172
Italy	61.402	61.379	61.349	61.32	61.283	61.24	61.192	61.14
Spain	47.1	47.136	47.161	47.189	47.209	47.223	47.235	47.248
United Kingdom	67.466	67.763	68.052	68.335	68.604	68.858	69.102	69.338
EU-5 Population (M)	324	324	324	325	325	325	325	325
Prevalence in NA	3%	3%	3%	3%	3%	3%	3%	3%
Prevalence (patient)	8	8	8	8	8	8	8	8
Price / dose (€)	234	234	234	234	234	234	234	234
Total Eur Mkt exp	1 894	1 896	1 898	1 899	1 901	1 902	1 903	1 903
% Penetration (Crossject)	0%	0%	0%	1%	3%	6%	9%	10%
<b>Sales by partner (€)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>19</b>	<b>57</b>	<b>114</b>	<b>171</b>	<b>190</b>
Volume ZENEO (000)	-	-	-	81	244	488	732	813
Royalties	20%	20%	20%	20%	20%	20%	20%	20%
Royalties	-	-	-	4	11	23	34	38
<b>Total sales by partner</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>33</b>	<b>100</b>	<b>201</b>	<b>303</b>	<b>338</b>
<b>Crossject Revenue (Royalties)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>7</b>	<b>20</b>	<b>40</b>	<b>61</b>	<b>68</b>
<b>Total Volume to provide (000)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>121</b>	<b>363</b>	<b>728</b>	<b>1 095</b>	<b>1 219</b>
Royalties paid	-	-	-	-0.5	-1.6	-3.2	-4.8	-5.4

Table 20 - Source: ODDO BHF Securities



# A FREE OPTION FOR OVER HALF OF THE CURRENT PIPELINE

We have decided to model only the company's current priorities for the time being: 1/ the supply of ZENEO Midazolam as part of its agreement with BARDA, 2/ the marketing of ZENEO Midazolam for epilepsy, 3/ ZENEO Hydrocortisone for adrenal insufficiency and 4/ ZENEO Adrenaline. The remainder of the portfolio, which could reach the market by 2026, will be included as clinical and regulatory advances and partnerships are secured. This conservative approach has the advantage of demonstrating a "floor" value for the company, which may change significantly depending on announcements.

## ZENEO Naloxone as an Opioid Antidote

### Opioid abuse continues to present major health risks

An overdose of opioids, such as oxycodone, morphine or heroin, is a dangerous condition that can lead to emergency hospitalisation as a result of acute intoxication. Opiate overdose is characterised by pinpoint pupils, a slowing of the respiratory rate and a reduced level of consciousness that can lead to coma. An overdose can be fatal as a result of severe respiratory depression if no action is taken.

According to WHO (World Health Organisation) estimates, in 2021, nearly 60 million people have had recourse to opioids, representing 1.2% of the world's population. Opioids are responsible for two-thirds of all drug-related deaths. By way of example, the US recorded c.80,000 deaths as a result of opioid overdoses in 2021, around four times more than in 2010.

### Number of deaths linked to opioid overdose in the US

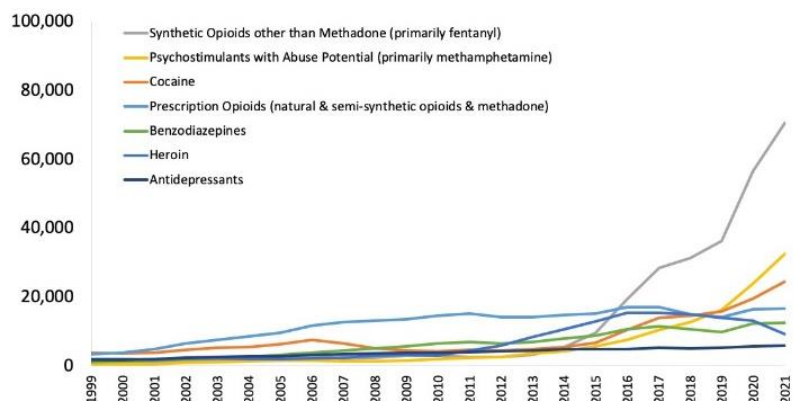


Chart 21 - Source: Centers for Disease Control and Prevention, National Center for Health Statistics



## Naloxone as the standard of emergency care

A CDC report conducted in 21 US states shows that the rate of emergency department admissions related to opioid overdoses has risen from 98.1 per 10,000 EMS (emergency medical services) visits in 2018 to 179.1 in 2022. Note that this figure may be underestimated, as many victims of non-fatal opioid overdose refuse to be taken to emergency departments.

Patient management depends on vital signs. In most cases, injection of naloxone is crucial as soon as possible to reverse respiratory depression, whether administered intravenously, intramuscularly, subcutaneously or via the endotracheal tube. Naloxone is a pure opioid receptor antagonist that blocks the effects of opioids on the body. It acts rapidly after administration, restoring breathing within 2-5 minutes. The effect of naloxone lasts from 30 to 90 minutes, whereas that of opioids may persist for longer. Consequently, new doses of naloxone should be given according to patients' symptoms.

### Treatment algorithm for opioid overdose

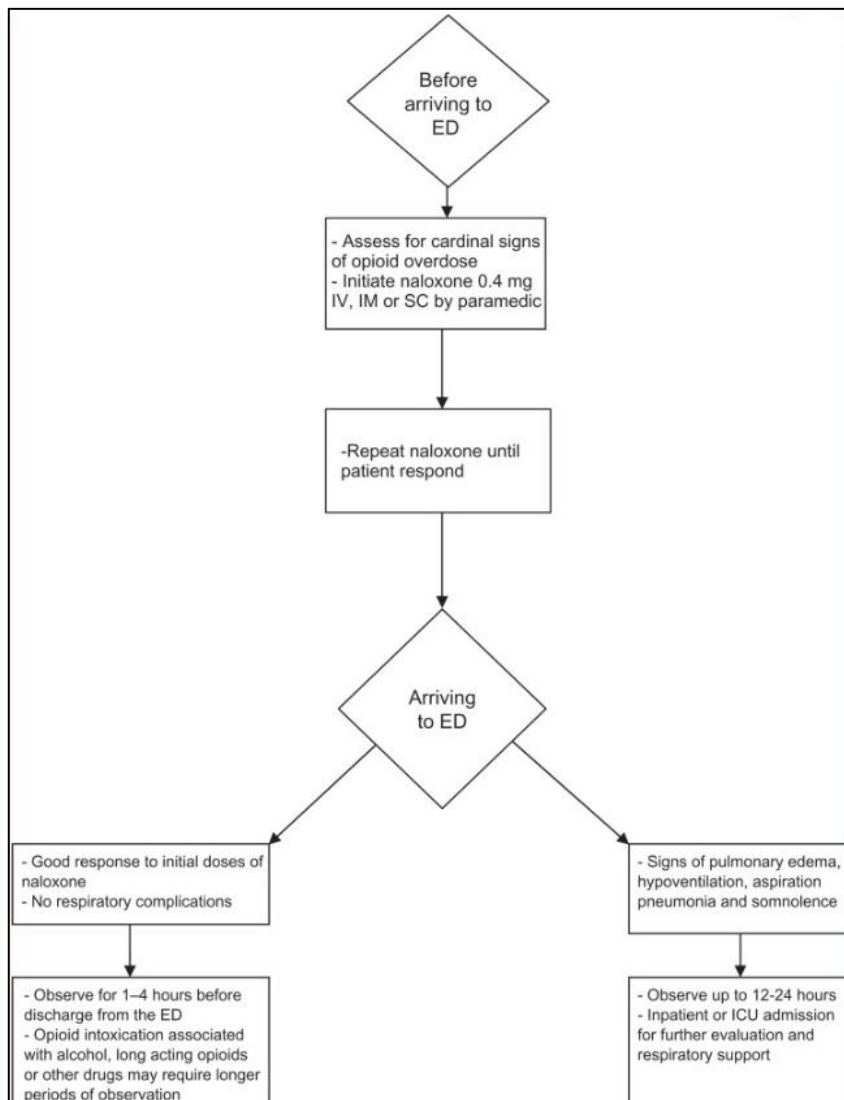


Chart 22 - Source: *Illicit Opioid Intoxication: Diagnosis and Treatment*



## A highly competitive market characterised by robust growth

Naloxone was originally approved by the FDA for the treatment of opioid overdose in 1971. Generic versions of the drug are therefore available in North America and Europe. Worldwide, the naloxone market is estimated at \$1.15bn in 2022 and is expected to reach \$ 2.75bn by 2031 (10.2% CAGR) mainly due to an increase in the number of cases.

Several forms of naloxone are available on the market:

- **Intravenous:** naloxone is administered in hospital, with the onset of action in 1-2 minutes and duration of effect of up to 45 minutes. Doctors usually start with a low dose of 0.05mg to 0.1mg IV, then gradually increase the dose to reduce the risk of withdrawal symptoms.
- **Intramuscular or subcutaneous:** this method is mainly intended for chronic addicts who have taken high doses of opiates, which we believe could be targeted by Crossject's auto-injector. A higher dose of naloxone (2mg) can be administered every 3 minutes up to 10mg. Opiate toxicity is reversed in 5-10 minutes, with a duration of effect of 30 to 120 minutes. Note that the FDA approved the first generic version of the pre-filled auto-injector, Evzio (0.4mg/0.4 mL or 2mg/0.4 mL), developed by Kaleo (a private company based in the US) in 2018 at a price of around \$ 4,000 for two doses.
- **Intranasal:** data have shown that intranasal administration is as effective as intramuscular administration in the pre-hospital setting. Nacran, the first nasal spray (4mg/0.1mL) developed by Emergent Biosolutions, was approved in 2015 by the FDA, at a price of \$ 56.88 per two sprays. The product generated sales of \$ 314m in 2020 ahead of the arrival of generics from Teva and Sandoz in 2021. In addition, Kloxxado, an 8mg dose developed by Hikma Pharmaceuticals, has been approved for 2021.

There are also two other opioid antagonists, nalmefene and naltrexone, to treat opioid overdose.

## ZENEO naloxone adapted to the treatments of overdoses in emergencies

Despite the fierce competition in the market, we identify several competitive advantages of ZENEO naloxone as an ideal opioid overdose solution over other alternatives:

- Flexibility of administration, regardless of the location of the emergency, especially compared with intravenous administrations.
- An ergonomic system designed for up to 70ml of the dose, potentially reducing the need for repeated dosages in case of recurrent symptoms.
- The speed and simplicity of pre-filling in seconds by intramuscular administration without a needle, compared with nasal spray, with which patients are likely to suffer from vomiting.

It is worth noting that the first 4mg over-the-counter (OTC) naloxone nasal spray was approved in March, which could strengthen Nacran's dominant position in this market. At this stage, the company is still looking for partners to continue the development of this product.



## ZENEO Terbutaline in the treatment of severe asthma attack

### An obvious emergency for severe asthma attacks

Asthma is a chronic lung disease resulting from inflammation and shrinkage of the muscles around the airways. According to the WHO, this disease affects 262 million people worldwide, causing 455,000 premature deaths each year. Note that 10% of asthmatics suffer from severe asthma. Individuals with mild asthma use inhalers for asthma attacks, while moderate to severe asthmatics use inhalation chambers or nebulizers. However, about 5,000 people go to ER as a result of an asthma attack, 1,000 people are hospitalised and 11 die from it every day in the US.

### Bronchodilators remain the 1L treatment

Management is based on the recognition of a moderate, severe or even life-threatening asthma exacerbation.

Initial care management involves administration of oxygen, SABA (short-acting beta-2-stimulant/bronchodilator) and SCS (systemic corticosteroids) or ICS (inhaled corticosteroids) at high doses in some patients. In case of non-response to primary treatment and signs of worsening ventilation, secondary alternatives may be considered, including epinephrine, magnesium sulphate, intubation, etc.

Note that salbutamol and terbutaline are the most frequently used SABAs in the event of an asthma attack because of their rapid action within a few minutes. SABA is a fast-acting bronchodilator that works by relaxing the muscles that surround the bronchi, facilitating the passage of air and thus relieving breathing quickly. These beta-2-stimulants can be administered by inhalation, nebulisation, or via IM/SC administration. Indeed, the inhaled form is expected to account for about 40% of the market for therapies for severe asthma.





### Asthma Attack Treatment Algorithm

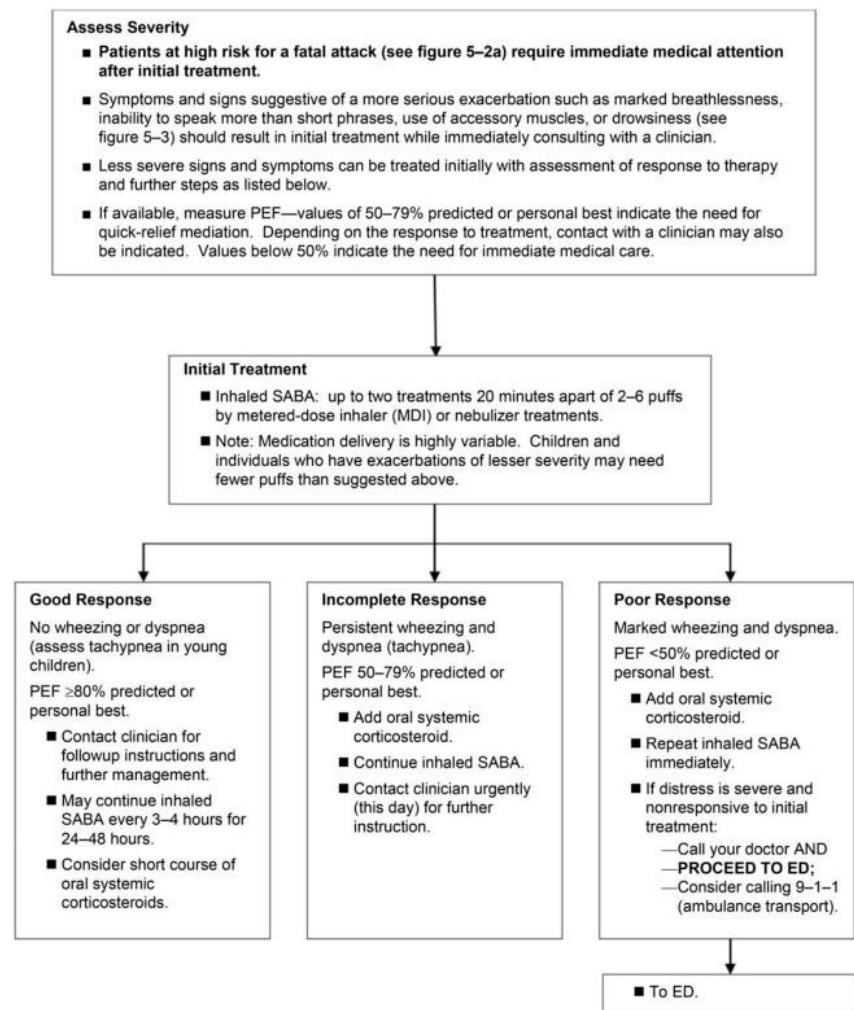


Chart 23 - Source: Acute asthma, prognosis, and treatment by Jennifer E. Ferguson, DO, Shiven S. Patel, MD, Richard F. Lockey, MD

### ZENEO terbutaline stands out in a competitive market

ZENEO terbutaline has been part of Crossject's portfolio as a solution for severe asthma attacks since 2017. The market for the treatment of severe asthma is expected to reach \$36bn with a CAGR of 5.1% by 2033. Key products on the market include Teva's Airomir Autohaler (salbutamol), GSK's Ventolin (salbutamol) and AstraZeneca's Bricanyl (terbutaline). Prices range from \$ 30 to \$ 50 per dose.

To date, we have not identified any terbutaline auto-injectors for the treatment of severe asthma attacks. We therefore believe that the speed of injection and the potentially prolonged duration of effect of ZENEO terbutaline (vs inhalers and nebulisers) should make it an optimal alternative to other forms.



Perception of Crossject's portfolio according to management

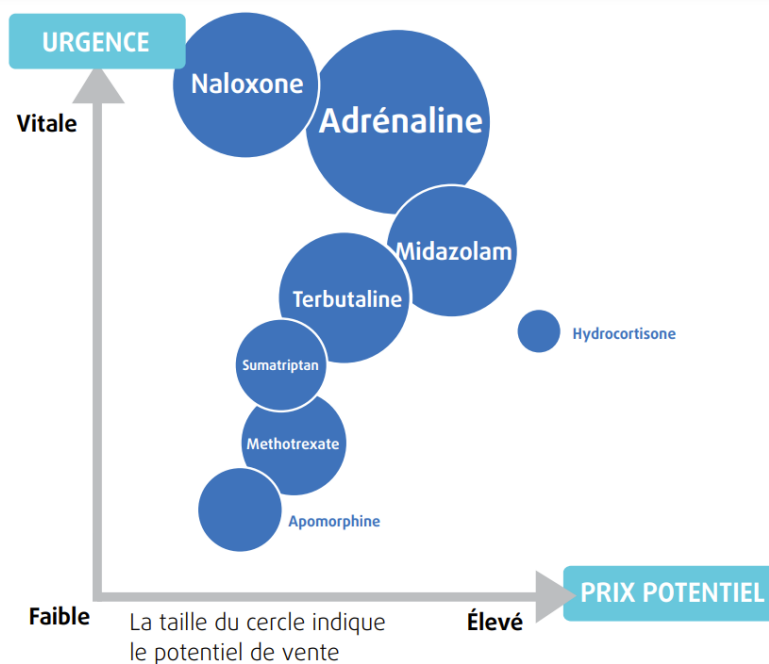


Chart 24 - Source: Crossject

## ZENEO Sumatriptan for the treatment of severe migraines

### Severe migraine and cluster headache

Approximately 92 million people worldwide are affected by migraines or headaches. Only 45% of them have been diagnosed, and 19 million patients suffer from severe forms (source: ANAES recommendations in 2012). Cluster headache (AVF) is rare (0.1% of the population). It manifests as a sharp pain most often felt around one eye. This pain occurs in attacks, with periods of several weeks between each attack. In about 10% of cases, AVF can become chronic.<sup>1</sup>

Migraine management relies on the use of non-specific medications such as analgesics and non-steroidal anti-inflammatory drugs, as well as specific medications such as triptans and ergot derivatives to relieve attacks. Sumatriptan was the first drug in the triptan class prescribed for severe migraines and short-term AVF alone or in combination with oxygen therapy.

In the case of AVF, sumatriptan is administered subcutaneously at the onset of pain (6mg) for relief for no more than 30 minutes. Treatment recommendations are based on two options:

≤ 2 seizures/day: SC sumatriptan, oxygen or both.

- > 2 seizures/day: dual therapy sumatriptan SC - oxygen or oxygen alone.

<sup>1</sup> Crossject <https://www.crossject.com/en/therapeutic-areas/migraines-and-cluster-headaches>



Management of cluster headaches

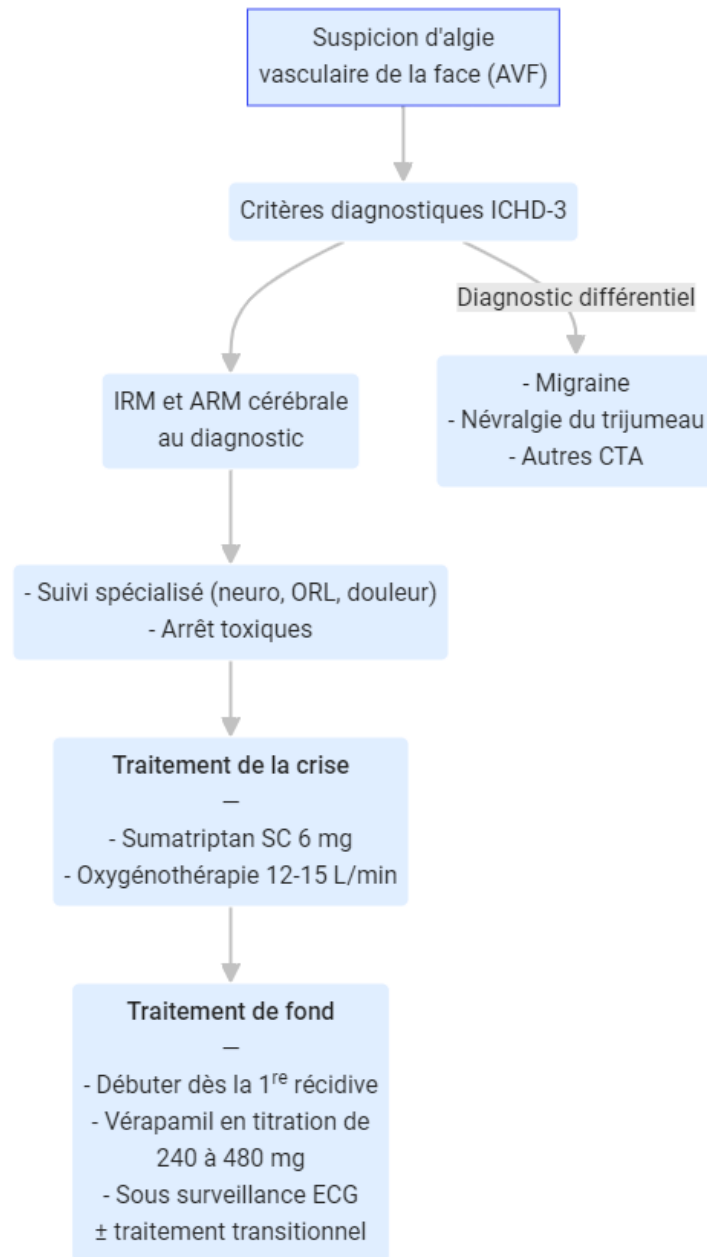


Chart 25 - Source: Dr JB Fron according to SFEMC 2014.<sup>2</sup>

A substantial market by volume and value

The global market for severe migraines is expected to be worth \$ 14bn in 2028, up from \$ 8bn in 2021. Triptans account for about 46%<sup>3</sup> of the market in 2021, and sumatriptan alone accounts for about 70%<sup>4</sup> of the triptan market.

Traditional oral and nasal forms dominate the triptan market with 90%. The injectable form of sumatriptan accounts for about 10% of the market.

<sup>2</sup> <https://recomedicales.fr/recommandations/algie-vasculaire-face/#:-:text=La%20prise%20en%20charge%20et,nombre%20de%20prises%20de%20traitements>  
<sup>3</sup> <https://www.globenewswire.com/fr/news-release/2023/03/10/2624811/0/en/Global-Acute-Migraine-Drugs-Market-Report-2023-A-14-06-Billion-Market-by-2028-Featuring-Key-Players-Eli-Lilly-and-Co-GSK-Bayer-J-J-Teva-AbbVie-Novartis-Merck-Pfizer-Boehringer-Ingelheim.html>  
<sup>4</sup> <https://journals.sagepub.com/doi/full/10.1177/0333102421991809>



There are sumatriptan nasal sprays such as GSK's Imitrex, and its generic Tosymra approved in 2019 by the FDA and manufactured by Dr. Reddy's laboratories.

There is also an injectable form of Imitrex, as well as generics in the form of pre-filled pens manufactured by Teva and Sun pharma.

It is important to point out that, according to studies, injectable forms are associated with faster results for emergency treatment. The time required to reach peak concentration (Tmax) is between 10 to 15 minutes for sumatriptan SC and up to 15 minutes for nasal sprays.

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### What's the difference with Zogenix's auto-injector?

It is important to note that a drug similar to ZENEO existed: Sumavel DosePro, a needle-free sumatriptan pre-filled auto-injector. It was initially developed by Zogenix and launched in co-promotion with Astellas in the US in 2010. After two unsuccessful partnerships with Astellas and Mallinckrodt, which ended in 2012 and 2014 respectively, the rights to the Sumavel Dose Pro were sold to Endo in 2014. Although the DosePro had a promising market breakthrough in 2010, sales stagnated two years after launch and declined with Endo. Eventually, the product was permanently withdrawn from the market by Endo in 2018.

The adaptability and efficiency of Zeno's system are assets to attract strategic collaborations. Note that Zogenix's problems are specific to the company (mismatch between the industrial and commercial models) and cannot be transposed to Crossject..

## ZENEO MTX for the Treatment of Chronic Rheumatoid Arthritis

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### A well-known disease

Rheumatoid arthritis is a chronic, systemic disease involving different pro-inflammatory cytokines attacking the joints. In 2019, 18 million people were affected by rheumatoid arthritis, 70% of whom were women<sup>5</sup>

As a first-line treatment, it is recommended to use methotrexate, which is the standard benchmark treatment. The starting dose of methotrexate is 10 mg weekly subcutaneously or intramuscularly, but should be adjusted according to the patient's body mass index (BMI) and renal function. Approximately 60% of people with rheumatoid arthritis are currently using or have used methotrexate<sup>6</sup>

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<sup>5</sup> <https://www.who.int/news-room/fact-sheets/detail/rheumatoid-arthritis>

<sup>6</sup> <https://www.hopkinsarthritis.org/patient-corner/drug-information/methotrexate-injection/>



## A highly competitive market

On the market, there are first-generation auto-injectors such as Metoject, as well as improved models such as Rasuvo. However, the ZENEO device stands out for its ease of use, ergonomics, needle-free profile and minimal effort required.

We believe this is particularly differentiating given that the nature of the disease makes handling syringes difficult.

Crossject has entered into three partnerships to ensure good commercial geographical coverage, collaborating with Sayre Therapeutics for the Indian subcontinent and Xi'an Xintong Pharmaceutical for future commercialisation in China. Apart from Asia, the US remains the main market targeted by the company.

We believe that the launch of the ZENEO MTX is not a priority for Crossject at present, although its competitive advantage in terms of design and efficiency suggests that the device could capture a share of the injectable methotrexate market.



## ALCJ.PA | ALCJ FP Biotechnology | France

**Outperform**

Price 4.28 €

Upside 65.89%

TP 7.10 €

	12/18	12/19	12/20	12/21	12/22	12/23e	12/24e	12/25e
<b>PER SHARE DATA (€)</b>								
Adjusted EPS	-0.56	-0.29	-0.37	-0.30	-0.30	-0.57	0.45	0.52
<b>Reported EPS</b>	<b>-0.56</b>	<b>-0.29</b>	<b>-0.37</b>	<b>-0.30</b>	<b>-0.30</b>	<b>-0.57</b>	<b>0.45</b>	<b>0.52</b>
Growth in adjusted EPS	-	ns	ns	ns	ns	ns	ns	16.8%
Net dividend per share	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
FCF to equity per share	-0.59	-0.41	-0.44	-0.35	-0.32	-0.47	0.30	0.51
Book value per share	0.09	0.12	-0.04	-0.15	0.07	-0.50	-0.05	0.47
Number of shares market cap (m)	19.09	24.37	26.54	36.52	37.24	37.24	37.24	37.24
Number of diluted shares (m)	19.09	24.37	26.54	36.52	37.24	37.24	37.24	37.24
<b>VALUATION (€m)</b>								
12m highest price (€)	4.62	3.16	4.24	4.01	4.67	4.95		
12m lowest price (€)	1.06	1.18	1.15	2.47	1.69	3.25		
(*) Reference price (€)	3.13	1.84	2.61	3.05	2.87	4.28	4.28	4.28
Capitalization	59.7	44.9	69.3	112	107	159	159	159
Restated Net debt	5.3	5.1	16.0	15.6	8.1	25.8	14.7	-4.5
Minorities (fair value)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Financial fixed assets (fair value)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Provisions	0.7	0.8	2.0	2.0	3.3	1.8	1.8	1.8
<b>Enterprise Value</b>	<b>65.6</b>	<b>50.9</b>	<b>87.3</b>	<b>129</b>	<b>118</b>	<b>187</b>	<b>176</b>	<b>157</b>
P/E (x)	ns	ns	ns	ns	ns	ns	9.6	8.2
P/CF (x)	ns	ns	ns	ns	ns	ns	8.5	7.3
Net Yield	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
FCF yield	ns	ns	ns	ns	ns	ns	7.0%	12.0%
P/B incl. GW (x)	36.07	14.91	ns	ns	39.76	ns	ns	9.07
P/B excl. GW (x)	36.07	14.91	ns	ns	39.76	ns	ns	9.07
EV/Sales (x)	18.61	8.49	15.24	19.07	12.16	100	4.10	3.25
EV/EBITDA (x)	ns	ns	ns	ns	ns	ns	7.2	5.5
EV/Current EBIT (x)	ns	ns	ns	ns	ns	ns	7.9	6.0
(*) historical average price								
<b>PROFIT AND LOSS (€m)</b>								
Sales	3.5	6.0	5.7	6.8	9.7	1.9	42.9	48.3
EBITDA	-8.6	-5.0	-6.7	-7.3	-8.0	-15.9	24.3	28.3
Depreciations	-3.0	-3.6	-3.9	-4.5	-5.3	-5.3	-2.1	-2.4
<b>Current EBIT</b>	<b>-11.6</b>	<b>-8.6</b>	<b>-10.7</b>	<b>-11.8</b>	<b>-13.3</b>	<b>-21.2</b>	<b>22.2</b>	<b>25.9</b>
Published EBIT	-11.6	-8.6	-10.7	-11.8	-13.3	-21.2	22.2	25.9
Net financial income	0.8	1.5	0.8	1.0	2.1	0.0	0.0	0.0
Corporate Tax	0.0	0.0	0.0	0.0	0.0	0.0	-5.5	-6.5
Net income of equity-accounted companies	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Profit/loss of discontinued activities (after tax)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Minority interests	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Attributable net profit	-10.7	-7.2	-9.8	-10.8	-11.2	-21.2	16.6	19.4
<b>Adjusted attributable net profit</b>	<b>-10.7</b>	<b>-7.2</b>	<b>-9.8</b>	<b>-10.8</b>	<b>-11.2</b>	<b>-21.2</b>	<b>16.6</b>	<b>19.4</b>
<b>BALANCE SHEET (€m)</b>								
Goodwill	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other intangible assets	4.7	6.3	7.5	9.1	10.7	10.7	10.7	10.7
Tangible fixed assets	6.3	5.8	6.8	7.1	7.7	2.5	2.0	1.6
WCR	-3.8	-3.6	2.0	-4.6	-5.0	-4.7	1.2	2.0
Financial assets	0.3	0.5	0.6	0.5	0.7	0.7	0.7	0.7
Ordinary shareholders equity	1.7	3.0	-1.1	-5.4	2.7	-18.5	-1.9	17.6
Minority interests	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Shareholders equity	1.7	3.0	-1.1	-5.4	2.7	-18.5	-1.9	17.6
Non-current provisions	0.7	0.8	2.0	2.0	3.3	1.8	1.8	1.8
<b>Net debt</b>	<b>5.3</b>	<b>5.1</b>	<b>16.0</b>	<b>15.6</b>	<b>8.1</b>	<b>25.8</b>	<b>14.7</b>	<b>-4.5</b>
<b>CASH FLOW STATEMENT (€m)</b>								
EBITDA	-8.6	-5.0	-6.7	-7.3	-8.0	-15.9	24.3	28.3
Change in WCR	-1.0	-1.7	-0.5	-0.3	0.4	-1.7	-6.0	-0.8
Interests & taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Others	1.6	1.2	1.7	1.6	2.5	0.0	-5.5	-6.5
Operating Cash flow	-8.0	-5.5	-5.5	-6.1	-5.1	-17.6	12.8	21.1
CAPEX	-3.3	-4.4	-6.1	-6.7	-6.8	-0.1	-1.7	-1.9
<b>Free cash-flow</b>	<b>-11.3</b>	<b>-9.9</b>	<b>-11.6</b>	<b>-12.8</b>	<b>-11.9</b>	<b>-17.7</b>	<b>11.1</b>	<b>19.1</b>
Acquisitions / disposals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Dividends	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net capital increase	4.0	3.2	0.0	0.0	7.1	0.0	0.0	0.0
Others	1.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Change in net cash	-5.7	-6.8	-11.6	-12.8	-4.8	-17.7	11.1	19.1
<b>GROWTH MARGINS PRODUCTIVITY</b>								
Sales growth	-	70.0%	-4.4%	18.2%	43.5%	-80.8%	ns	12.5%
<b>Lfi sales growth</b>	<b>-</b>	<b>70.0%</b>	<b>-4.4%</b>	<b>18.2%</b>	<b>43.5%</b>	<b>-80.8%</b>	<b>ns</b>	<b>12.5%</b>
Current EBIT growth	-	ns	ns	ns	ns	ns	ns	16.8%
Growth in adjusted EPS	-	ns	ns	ns	ns	ns	ns	16.8%
Net margin	ns	ns	ns	ns	ns	ns	38.8%	40.3%
<b>EBITDA margin</b>	<b>ns</b>	<b>-83.4%</b>	<b>ns</b>	<b>ns</b>	<b>-82.6%</b>	<b>ns</b>	<b>56.8%</b>	<b>58.7%</b>
<b>Current EBIT margin</b>	<b>ns</b>	<b>ns</b>	<b>ns</b>	<b>ns</b>	<b>ns</b>	<b>ns</b>	<b>51.8%</b>	<b>53.7%</b>
CAPEX / Sales	-92.9%	-73.4%	ns	-99.4%	-69.8%	-4.0%	-4.0%	-4.0%
WCR / Sales	ns	-59.8%	34.8%	-67.8%	-51.1%	ns	2.9%	4.2%
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	25.0%	25.0%
Normative tax rate	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Asset Turnover	-	0.8	0.5	0.5	0.8	0.2	3.8	3.4
<b>ROCE post-tax (normative tax rate)</b>	<b>-</b>	<b>-82.7%</b>	<b>-64.7%</b>	<b>-63.4%</b>	<b>-79.5%</b>	<b>ns</b>	<b>ns</b>	<b>ns</b>
ROCE post-tax hors GW (normative tax rate)	-	-82.7%	-64.7%	-63.4%	-79.5%	ns	ns	ns
ROE	-	ns	ns	ns	ns	ns	ns	ns
<b>DEBT RATIOS</b>								
Gearing	319%	170%	ns	ns	302%	ns	ns	-25%
Net Debt / Market Cap	0.09	0.11	0.23	0.14	0.08	0.16	0.09	-0.03
<b>Net debt / EBITDA</b>	<b>-0.61</b>	<b>-1.02</b>	<b>-2.38</b>	<b>-2.13</b>	<b>-1.01</b>	<b>-1.62</b>	<b>0.60</b>	<b>-0.16</b>
EBITDA / net financial charges	-11.7	45.4	-26.9	-8.3	-25.2	ns	ns	ns

Sources: ODDO BHF Securities, SIX



• **Valuation method**

Our target prices are established on a 12-month timeframe and we use three valuation methods to determine them. First, the discounting of available cash flows using the discounting parameters set by the Group and indicated on ODDO BHF' website. Second, the sum-of-the-parts method based on the most pertinent financial aggregate depending on the sector of activity. Third, we also use the peer comparison method which facilitates an evaluation of the company relative to similar businesses, either because they operate in identical sectors (and are therefore in competition with one another) or because they benefit from comparable financial dynamics. A mixture of these valuation methods may be used in specific instances to more accurately reflect the specific characteristics of each company covered, thereby fine-tuning its evaluation.

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• **Our stock market recommendations**

Our stock market recommendations reflect the RELATIVE performance expected for each stock on a 12-month timeframe.

Outperform: performance expected to exceed that of the benchmark index, sectoral (large caps) or other (small and mid caps).

Neutral: performance expected to be comparable to that of the benchmark index, sectoral (large caps) or other (small and mid caps).

Underperform: performance expected to fall short of that of the benchmark index, sectoral (large caps) or other (small and mid caps).

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**Recommendation and target price changes history over the last 12 months for the company analysed in this report**

Date	Reco	Price Target (EUR)	Price (EUR)	Analyst
01/11/23	Outperform	7.10	4.07	Martial Descoutures

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		Outperform	Neutral	Underperform
Our whole coverage	(679)	53%	36%	11%
Liquidity providers coverage	(81)	51%	36%	14%
Research service coverage	(49)	63%	24%	12%
Investment banking services	(25)	52%	40%	8%

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