Press Release

Crossject reports financial results and business highlights for the first six months of 2024

- Available cash €5.95 million, up from €2.3 million on December 31, 2023
- Reports stable investments in R&D and consolidation of operating income from BARDA
- Company on track to successfully file for the Emergency Use Authorization for its epilepsy rescue therapy in early 2025

Dijon, France, September 23, 2024 18:00 CET -- Crossject (ISIN: FR0011716265; Euronext: ALCJ), a specialty pharma company developing the award-winning needle-free ZENEO® auto-injector to deliver life-saving medicines in emergency situations, today reports its financial results for the six months ending June 30, 2024, as well as an update on business highlights.

Over the reporting period, Crossject has continued to engage with U.S. regulators and U.S. Biomedical Advanced Research and Development Authority (BARDA), reaffirming its strategy to focus on obtaining regulatory approvals and strengthening its U.S. commercial footprint, as it expects to be able to reach profitability based on U.S. sales of Zepizure® alone. The company expects to file for an Emergency Use Authorization (EUA) for ZEPIZURE® early next year and to receive a response from the FDA not much later. A positive answer will allow the company to fulfil its first sales order from BARDA[1]. In parallel, Crossject expects to file a New Drug Application (NDA) for ZEPIZURE® in the first half of 2025, which would grant marketing approval for a general commercialization strategy in the US.

"Crossject has been accelerating its progress, strengthening its balance sheet, and reaching several new milestones over the past year. We are now at a stage where we can look ahead to our first product candidate, ZEPIZURE®, coming to market," said Patrick Alexandre, CEO of Crossject. "We are looking forward to a number of important steps to increase the value of our business over the course of 2025. The $92 million contract with the U.S. BARDA (totalling $155 million if all options are exercised) is a cornerstone of the commercialisation strategy in our largest market, in addition to which we have strengthened our senior executive team in the U.S. with two recent additions."

The company is working on the final development stages for ZEPIZURE® in epileptic crises, including an upcoming 505(b)(2) pivotal bioequivalence study, which the company expects to be the final step for its U.S. NDA, and which follows on from the successful completion of a bioequivalence clinical study in 2022, the results of which were published in May 2024.

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

The company also took several registration and pre-commercialization steps for Zepizure® in the US, supported by Syneos Health, a leading biopharmaceutical solutions company, and continued to build its infrastructure in North America. The company appointed several new senior executives, including Dr Dan Chiche, an experienced life sciences executive, as Chief Medical Officer, North America. In Europe, Crossject extended the geographic coverage of its 2023 commercialization agreement for ZEPIZURE®, which now covers 11 European countries.

During the first half of 2024, Crossject also strengthened its balance sheet. In February, it issued a convertible and/or repayable bond in two tranches to Heights Capital Management, an institutional investor specialized in growth companies, for a maximum of €12 million, out of which the company has cashed in €6.3 million. In June, the company raised approximately €7.6 million net through a rights issue aimed at supporting the development of ZEPIZURE®. Given the ongoing contracts, including the monthly invoicing to BARDA, and the strong visibility Crossject has gained in recent months, the company is confident in its ability to secure the necessary financing to continue its development.

Finally, in terms of clinical progress, Crossject published new data on ZEPIZURE® in an article in *Neurology and Therapy* in May, outlining the full results of a clinical study conducted in 2022, demonstrating that ZENEO® allows injecting seizure management therapy midazolam intramuscularly, on bare skin or through clothing, to the same extent as a syringe equipped with a 30mm needle (Dormicum®). Crossject also highlighted a two-fold lower variability as compared to that observed for other administration routes, such as intranasal.

Outside the reporting period, from July 1, 2024 onwards, Crossject added more important developments to the list.

- In July, Crossject completed a new registration batch of ZEPIZURE® at the facility of Eurofins, the CDMO designated to ensure fill and finish activities for deliveries to BARDA.
- Also that month, the French government awarded €6.9 million to Crossject, as part of a call for projects under the France 2030 Plan, which aims to support companies that demonstrate exceptional potential for growth and innovation.
- In August, Crossject named Tony Tipton, an executive with extensive commercialization experience in the pharmaceutical business, into the role of U.S. Chief Operating Officer.

See also appendices 1 (income statement), 2 (balance sheet, assets) and 3 (balance sheet, liabilities).

About Crossject

Crossject SA (Euronext: ALCJ; www.crossject.com) is an emerging specialty pharma company. It is in advanced regulatory development for ZEPIZURE®, an epileptic rescue therapy, for which it has a $60 million contract with the U.S. Biomedical Advanced Research and Development Authority (BARDA). ZEPIZURE® is based on the Company's award-winning needle-free autoinjector ZENEO®, designed to enable patients and untrained caregivers to easily and instantly deliver emergency medication via intramuscular injection on bare skin or even through clothing. The Company's other products in development include rescue therapies for allergic shocks, adrenal insufficiencies, opioid overdose and asthma attacks.

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Appendix 1

Income statement, H1 2024 vs H1 2023

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

Accounts were approved by the Executive Board on September 23, 2024, and presented to the Supervisory Board on the same day.

(1) The variation in capitalized production and the corresponding depreciation is related to the change in the valuation of R&D expenses capitalized at the end of the 2023 fiscal year.

For the first half of 2024, Crossject's operating income from its advanced regulatory development work supported by BARDA amounted to $3.3 million, slightly up from $3.2 million in the same period in 2023. R&D investments remained stable. The net result variation was primarily due to the depreciation of securities, with no significant changes attributable to operational activities.

Appendix 2

Balance sheet assets, 30 June 2024 vs 31 December 2023

(Thousands of euros)	30/06/2024	31/12/2023	Difference
FIXED ASSETS			
R&D	10 238	10 730	-492
Patent and trademarks	0	0	0
Other intangible assets	0	0	0
Land, property, plant and equipment	2 240	2 750	-510
Assets under construction	3 821	2 942	879
Financial assets	996	1 544	-548
TOTAL FIXED ASSETS	**17 295**	**17 966**	**- 671**
CURRENT ASSETS			
Raw materials, other supplies	2 021	1 648	373
Work in process	2 364	1 485	879
Other receivables	4 066	4 778	-712
Available cash	5 952	2 304	3 648
Prepaid / deferred expenses	1 430	460	971
TOTAL CURRENT ASSETS	**15 833**	**10 675**	**5 158**
TOTAL ASSETS	**33 128**	**28 641**	**4 487**

Appendix 3

Balance sheet liabilities, 30 June 2024 vs 31 December 2023

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