Press Release

Crossject advances in its U.S. Strategy and reports Financial Results for 2023

- Increase in visibility in its regulatory and commercialization prospects in the U.S. since latest interactions with the FDA
- Expectation to receive U.S. Emergency Use Authorization (EUA) for ZEPIZURE® in Q1 2025
- Expectation to complete U.S. New Drug Application (NDA) for ZEPIZURE® in H1 2025
- Reinforcement of supply chain [with addition of a second fill-and-finish CDMO]
- Reporting of a reduced Net loss of €8.5 million versus €11.2 million in 2022

Dijon, France April 2, 2024, 10:30am CET -- Crossject (ISIN: FR0011716265; Euronext: ALCJ), a specialty pharma company developing needle-free auto-injectors for emergency situations, announces progress on multiple fronts in its clinical development, registration and U.S. commercial strategy and reports its financial results for the year ending December 31, 2023.

Patrick Alexandre, CEO of Crossject, announces:

Crossject is approaching a number of important value inflection points, which have the potential to transform our company and deliver substantial shareholder value.

Our $92 million contract with the Biomedical Advanced Research and Development Authority (BARDA) (up to $155 million if all options are exercised) is progressing. This contract, with the Department of Health and Human Services; Administration for Strategic Preparedness and Response; BARDA under contract number 75A50122C00031, includes up to $32 million for the advanced development of ZEPIZURE® through approval by the FDA for the treatment of status epilepticus seizures in adults and children over the age of 2. It also includes the procurement of $60 million of ZEPIZURE® to the U.S. Government once it has received Emergency Use Authorization (EUA) from the FDA. These proceeds will contribute in a timely fashion to the deployment of ZEPIZURE® in epilepsy markets.

During recent interactions with the FDA, we have achieved better visibility on the next development steps for the U.S. regulatory pathway. We estimate that a response from FDA regarding the EUA will be received during Q1 2025.

In parallel, we expect to file in H1 2025 for an NDA of ZEPIZURE®. We are firmly focused on the final development stages for epileptic crises, including an upcoming 505(b)(2) pivotal bioequivalence study, as part of the NDA that we anticipate to file in H1 2025. We are also working on activities related to its registration and pre-commercialization in the United States, since Crossject intends to retain U.S. commercial rights to ZEPIZURE®. We have been working in close collaboration with Syneos Health, a leading contract research, market access and commercialization services organization, which we engaged in January. Together, we are working with the aim to ensure a smooth and rapid launch of ZEPIZURE® upon receiving regulatory approval from the Food and Drug Administration (FDA).

We intend to file our NDA application for the Status Epilepticus indication under FDA's 505(b)(2) regulatory pathway.. This is a streamlined NDA process in which we can rely on investigations previously conducted by third parties for an FDA approved reference product, and where we will only need to demonstrate bioequivalence with such a product. In our upcoming pivotal study, we intend to replicate the comprehensive positive bioequivalence results already demonstrated in our precedent study released on 2 November 2022, which will be used for the EUA. In this randomized crossover study, ZEPIZURE® demonstrated bioequivalence to a predicate injectable marketed in Europe. Based on these and other data, we are confident that the ZENEO® platform will continue to demonstrate its ability to mimic intramuscular injections from traditional injectables with a high accuracy and low variability. These ZENEO features, now well validated, will be essential to limit development and regulatory risks. More importantly, we also expect them to drive market acceptance versus traditional injectables, and versus other delivery methods, including intranasals, which are known for their intrinsic transmucosal pharmacokinetic variability, compounding with the admnistration challenges customarily incurred during crises.

Our market opportunity has been validated by the relative success of such intranasal products, promoted as "needle free". We look forward to reaching the market with our first unique solution in epilepsy, that is dependable and addresses the limitations of currently marketed products.

Our two main additional programs, ZENEO® Hydrocortisone and ZENEO® Adrenaline, are also progressing toward planned market authorization filings in 2025 and 2026 respectively.

The supply chain organization, including our new partner Eurofins Scientific as fill-and-finish CDMO (Contract Development and Manufacturing Organization), was discussed with BARDA and the FDA. Although it has led to further delay, we firmly believe that, today, our level of automation will not only strengthen our supply chain but also further secure the anticipated volumes for all our programs.

This combination of positive developments has served as a strong background for the continued strengthening of our balance-sheet, recently achieved through our €12 million financing with Heights Capital Management. As ZEPIZURE® progresses toward market authorizations, and as we also support our two main additional programs, we will continue to actively explore the best way to finance our maturing global operations throughout the rest of 2024.

Philippe Monnot, CEO and one of the founders of Gemmes Venture, our reference shareholder, has confirmed his support :

« With the recent evolutions in Crossject's supply chain and the constructive interactions with the FDA we trust that the Company can market its revolutionary products; we renew our trust in the Company and its management. »

I am grateful to you, our shareholders, for your unwavering attention and your continuing support of our efforts. Together, we have the opportunity to make a significant difference for patients and create value for our company.

Financials for 2023

Key financial information as of December 31, 2023

In 2023, we continued the financing of the development ZEPIZURE® and of the rest of our pipeline and infrastructure through multiple sources:

- BARDA invoicing: $6.7 million were invoiced as reimbursements of research and development expenses incurred in 2023, versus $1.8 million in 2022;
- Invoicing to distributor: € 145 thousand were collected as upfront payment upon signing of the agreement with AFT Pharmaceuticals, Ltd;
- Research tax credit: €2.4 million were collected in 2023 versus €2.0 million in 2022.
- Real estate leaseback transaction : €4.7 million were raised through a sale and leaseback transaction for two of its buildings with leasing payments spread over the following 12 years;
- Borrowings: 8 million proceeds from loans contracted in 2022 were collected.
- Convertible Bonds: All outstanding convertible bonds had been converted as of 31/12/2023.

In 2023, we accelerated our research and development and overall activities. As a result, we recorded a very substantial increase in operating income to €12.8 million, an increase of 32% over 2022.

The table below summarizes our income statement for the years ending 31 December 2023 and 2022:

€ thousands, as of 31 December*	**2023**	**2022**
Operating income	**12 826**	**9 718**
Operating expenses	**-25 126**	**-23 005**
Purchase of raw materials and supplies	-1 595	-498
Other purchases and external expenses	-8 869	-8 116
Personal expenses	-7 713	-7 424
Taxes and duties	-267	-176
Depreciation, amortisation and provision	-6 185	-6 358
Other expenses	-494	-433
Operating profit/loss	**-12 300**	**-13 288**
Financial income/expense	**-497**	**-319**
Exceptional income/expense	**1 463**	**228**
Corporate tax	2 867	2 222
Net profit/loss	**-8 467**	**-11 157**

**Audit in progress*

The Operating expenses increased by 9% in 2023 over 2022, a very moderate rise in relation to the increase of our operating income. Such increase resulted from our advancing in the research and development of ZEPIZURE and of our other programs as well as from the initial steps in building our US team and operations.

Other purchases and external expenses amounted to €8.9 million, compared with €8.1 million in 2022, as we have been maintaining the progress in our production work and third-party activities linked to the regulatory development of ZEPIZURE® as well as activities on other key programs in our pipeline.

As of 31 December 2023, Crossject had approximately 111 employees, an 11% increase compared with 2022. Personnel expenses amounted to €7.7 million in 2023 compared to €7.4 million in 2022, the increase is due to these new recruitments in 2023.

We reported an Operating loss of €12.3 million, compared with a loss of €13.3 million in 2022 with the relative stability reflecting our increased operating expenses and their partial offsetting by operating income.

We recorded net financial expenses of €0.5 million for 2023, compared to an expense of €0.3 million for 2022.

After taking into account an exceptional income of €1.5 million, provided primarily from the transaction of the real estate leaseback and a reversal of accounting provision, as well as the research tax credit for an amount of €2.9 million, we are reporting a Net loss for 2023 of €8.5 million versus a loss of €11.2 million in 2022.

Treasury position

As of 31 December 2023, we had a cash balance of €2.3 million.

From the beginning of 2024 we have made it a priority to explore all types of financings to pursue our research and development and overall activities. As of 28 February 2024, we raised a first financing of up to €12 million from Heights Capital Management, in two tranches, with the first tranche of €7 million extended at closing. That tranche may be supplemented by a second tranche of a maximum amount of approximately €5 million on our initiative and subject to compliance with certain conditions.

Based on our financial resources as of 31 March 2024 and taking into account ongoing historical relationships with our lenders and creditors, the Company is confident to be able to finance its business plan until September 2024. In 2024, the Company also intends to obtain material financings from its undisclosed European collaboration partner, for an amount of €0.5 million, €0.7 million from grants as well as from research tax credit payments related to the periods of 2023 and 2024.

As the prospects for ZEPIZURE® improve and as we dedicate resources to the research and development of our two main additional ZENEO product candidates, ZENEO® Hydrocortisone and ZENEO® Adrenaline, we will continue to actively explore the best ways to finance our maturing global operations in equity, debt, public financings and other kinds of financings throughout 2024.

Notable milestones in 2023

Non-dilutive financing

Crossject completed a combined non-dilutive financial transaction of €14 million to accelerate the company's development. The transaction includes various loans granted by its long-standing banks (Caisse d'Epargne and BNP), Société Générale and BPI, with amortization periods ranging from 5 to 10 years and with nearly 85% of the total available.

New licensing agreement on ZENEO® Midazolam epilepsy rescue therapy

Crossject signed an Australia & New Zealand commercial agreement with AFT Pharmaceuticals for ZENEO® Midazolam, its innovative rescue therapy for epileptic seizures. AFT Pharmaceuticals is a

particularly well-suited partner because of its strong regional presence and extensive experience with successful commercial launches.

Commercialization agreement in northern Europe

Under this agreement with an undisclosed strategic partner, Crossject will receive milestone payments of up to €1 million in total, upon marketing authorizations being granted in the partner's territories. Crossject will manufacture and sell ZEPIZURE® to its strategic partner with a markup that is a share of the gross profit (defined as net sales minus cost of goods).

Successful completion of European and U.S. audits

Crossject's manufacturing sites in Dijon and Gray (France) passed an annual ISO certification audit, expanded their scope of certification by the French Health Agency, and received positive feedback after an audit by BARDA on compliance of manufacturing ZENEO® Midazolam for the U.S. market.

Appointment of Daniel Teper as Director on the Supervisory Board

With a PhD in Pharmacy from Paris-Saclay University and an MBA from INSEAD, Daniel Teper is a U.S.-based pharmaceuticals industry leader and entrepreneur with a compelling background spanning the fields of marketing, capital markets, strategy and development.

hErOiSme early stage project

The French Ministry of Armed Forces (Ministère des Armées) selected the project offered by a research consortium to develop a new molecule for rescue therapies for hemorrhagic shock treatment with ZENEO® auto-injector. Many civilian and military lives could be saved by promptly stabilizing the condition of a person suffering from hemorrhagic shocks. Crossject and IDD, its long-term regulatory partner, have officially joined this 3-year-long research program with a total budget of EUR 800,000.

Initiation of coverage by ODDO-BHF

In November 2023, ODDO-BHF analysts rated Crossject as "Outperform" with a price target of €7.10, citing the significant advantages associated with the company's needle-free ZENEO® device.

Significant improvement in Gaïa ESG rating

Crossject's new score of 73/100 is significantly up from 60 last year and 46 in 2021. Crossject's Gaïa rating, compiled by EthiFinance ESG Ratings, increased across all four themes: governance, social, environment and external stakeholders. There were particularly notable improvements in the ratings for environment and external stakeholders' performance.

Events beyond the reporting period

Convertible bond financing of up to €12 million

The financing is in two tranches, from an entity managed by Heights Capital Management, in issued bonds convertible in new shares, with a conversion premium of 35%1, or repayable (in cash and/or stocks, according to the company's options) over 36 months at a rate of 7%. Heights Capital Management, Inc. is an institutional investor specialized in financing growing companies. The

financing is a sign of confidence in our industrial and market progress, particularly in North America.

Engagement of Syneos Health for U.S. commercial launch of ZEPIZURE®

Crossject engaged Syneos Health, a leading fully integrated biopharmaceutical solutions organization, to prepare for the commercial launch of ZEPIZURE® for epileptic seizures in the U.S. Under the agreement, Syneos Health will provide support in all pre-launch and launch activities for ZEPIZURE®. Syneos Health brings a strong U.S. presence and significant expertise in commercializing new therapies for Crossject.

Gender equality score reaches 96/100 in 2024

This is the third successive year the score has been above 90%. The Gender Equality Index is a tool to measure the progress of gender equality in the EU and is assessed by a score from 1 to 100, with 100 meaning full equality between women and men.

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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