Press release

# First-half 2022 results
## Achievement of major milestones in the first half
## On track for a change of dimension

Dijon, 20 September 2022

**CROSSJECT (ISIN: FR0011716265; Ticker: ALCJ), a specialty pharma company that is developing and will soon be marketing a portfolio of drug / device combinations for use in emergency situations,** is announcing its 2022 half-year results and issuing a business update.

Patrick Alexandre, Crossject CEO, said: *"Since the beginning of the year, Crossject has achieved significant milestones that amply reflect our ability to develop life-saving drugs. We are proud to be cooperating with BARDA,[1] which, by selecting us for a large-scale contract, has confirmed the potential of our ZENEO® Midazolam autoinjector, not only for epileptic seizures but also in the event of chemical attacks. We are also very pleased to have obtained ISO 13485 certification in August, in addition to the GMP[2] certificate of compliance issued by the ANSM[3] in 2021, once again demonstrating the high standards of our quality system. I would like to thank our teams for their commitment, which made these successes possible. Building on these achievements, our roadmap is unfolding, with the results of the ZENEO® Midazolam clinical trial expected in the autumn."*

## Major milestones

Over the period, Crossject confirmed a very strong acceleration in its rollout, achieving key milestones that have placed the company in a new configuration, with embedded growth potential validating years of R&D.

[1] Biomedical Advanced Research and Development Authority
[2] See press release dated 16 November 2021
[3] French National Agency for the Safety of Medicines and Health Products

## *Agreement with BARDA: ground-breaking commercial success with an agreement worth up to $155 million, including a first firm order*

On 17 June 2022, Crossject signed an agreement[4] with BARDA on ZENEO® Midazolam. In this context, the operational phase of the cooperation between BARDA and Crossject started in July.
In addition to regular meetings every other week, a delegation from BARDA came to Europe in August to discuss the recently awarded ZENEO® Midazolam project and to visit Crossject's headquarters and the three main manufacturing sites for ZENEO® Midazolam.
In addition, Crossject transmits monthly invoices to BARDA for the contractual activities linked to the advanced regulatory development of ZENEO® Midazolam.

BARDA funding includes:

- up to $32 million for advanced research studies and late-stage clinical development with the goal of obtaining regulatory approval (EUA[5] and full NDA[6] approval) for ZENEO® Midazolam autoinjectors for both adult and paediatric populations for the treatment of Status Epilepticus seizures (which can be caused by nerve agents);
- procurement orders for adult and paediatric ZENEO® Midazolam autoinjectors for the United States Government for a value of $60 million, invoiced upon shipment;
- options, to be exercised at the discretion of the US Government, for additional ZENEO® Midazolam procurement orders valued at up to $59 million, and U.S. Food and Drug Administration post-marketing commitments for up to $3 million.

The total value of the contract is $155 million if all options are exercised.

This project is being funded in whole or in part with Federal funds from the Administration for Strategic Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA), under Contract No. 75A50122C00031.

Currently, Crossject is not in talks or in a proposal process for projects other than ZENEO® Midazolam with BARDA, who is however developing a set of medical countermeasures that may become opportunities in the years to come.

## *Significant progress in the development of ZENEO® Midazolam and ZENEO® Hydrocortisone*

The development of ZENEO® Midazolam continues on schedule.

The safe and effective ergonomics of ZENEO® for rapid injection in emergencies has been further demonstrated by the results of a human factors study, initiated by Crossject, in the US. The results show that ZENEO® achieves 99.6% success on the criteria evaluated in the use scenario and an average of 43 seconds between the opening of the packaging and the injection.

[4] See press release dated 18 June 2022
[5] Emergency Use Authorization
[6] New Drug Application, the US equivalent of a Marketing Authorisation in Europe

In addition, the injection phase of the ZENEO® Midazolam bioequivalence clinical study was completed in July. The study's full results are expected in the autumn and will be included in the marketing authorisation applications for the regulatory authorities in Europe and the US.

As a reminder, as part of the above-mentioned agreement with BARDA on ZENEO® Midazolam, it is intended to submit an Emergency Use Authorization (EUA) application to the FDA[7] prior to the NDA applications. An EUA is a measure issued by the FDA in the event of a declared public health emergency to expedite the availability of medical products to treat victims in the population in the event of an incident or attack. EUA was used notably during the COVID-19 crisis, with approvals (diagnostics, vaccines, therapies) issued within weeks of submission.

The development of ZENEO® Hydrocortisone is ongoing. The next major steps are the human factors study specific to ZENEO® users experiencing acute adrenal insufficiency, the production of validation batches – also suitable for a clinical study – and the clinical bioequivalence study.
However, the production phase of the registration batches could be deferred by a few months, which would reposition the submission of marketing authorisation applications at the beginning of 2024.
As a reminder, the compliance of the industrial transposition batch of ZENEO® Hydrocortisone last March, the first milestone in the contractual relationship with Eton Pharmaceuticals, triggered the payment of $0.5 million.

For ZENEO® Epinephrine,[8] development is continuing, in particular with work aimed at improving stability over time.

The development of the other drugs in the portfolio continues, with prioritisation based on commercial opportunities.

## *ISO 13485 certification: a mark of recognition for the high standards of Crossject's quality system*

After obtaining the Good Manufacturing Practices certificate at the end of 2021, Crossject obtained ISO 13485[9] certification for its two sites in Gray and Dijon in August. This certification, a proactive process of compliance with an internationally recognised standard, further demonstrates Crossject's ability and commitment to develop and manufacture medicines using processes that meet the highest standards.
As a reminder, the scope of ISO 13485 certification covers the entire life cycle of the ZENEO® needle-free injection system: "Design, development and manufacture of a sterile, single-use needle-free autoinjector for drug delivery" for the Dijon site and "Manufacture of a single-use needle-free autoinjector for drug delivery" for the Gray site.

[7] Food and Drug Administration
[8] Epinephrine is the name used in the US for Adrenaline
[9] See press release dated 15 August 2022

### *Commercial negotiations benefit from recent progress*

Crossject notes that both existing and new commercial discussions benefit greatly from the increased visibility provided by the agreement with BARDA and ISO 13485 certification. The results of the clinical study for ZENEO® Midazolam, expected in the autumn, will further reinforce this visibility.

Crossject is also discussing cooperation outside its own product line. For example, a US pharmaceutical company is currently testing the ZENEO® autoinjector in a drug formulation compatibility study.[10] This study is part of the initial development of a life-saving emergency drug for pre-hospital administration by non-medical personnel.

Besides, the US Department of Defense (DOD) is funding the licensure of a Midazolam autoinjector with a non-retractable needle, corresponding to a long-established military use. Nevertheless, Crossject intends to continue discussions with the DOD for applications that meet emergency medicine needs.

## On track for a change of dimension

Following the achievement of several milestones in 2021 and early 2022, Crossject intends to continue rolling out its roadmap. Until the end of 2022, Crossject will focus on the following projects in particular:

- Publication of the main results of the clinical bioequivalence study for ZENEO® Midazolam as soon as they are known;
- Continuation of the BARDA agreement programme;
- Production of the ZENEO® units needed for MA applications;
- Preparation of the Emergency Use Authorization application for ZENEO® Midazolam in the United States;
- Signature of new commercial agreements.

To support its transformation, Crossject will mobilise all the necessary resources and will adapt its future financing methods (commercial revenue, contributions from strategic partners, grants and subsidies or financial transactions, etc.).

[10] See press release dated 15 September 2022

## Financial information as of 30 June 2022

| € thousand, as of 30 June | H1 2022 | H1 2021 |
|---|---|---|
| **Operating income** | **3,374** | **3,176** |
| **Operating expenses** | **10,333** | **9,380** |
| Purchases of raw materials and supplies | 248 | 245 |
| Other purchases and external expenses | 3,566 | 2,955 |
| Personnel expenses | 3,628 | 3,117 |
| Taxes and duties | 75 | 104 |
| Depreciation, amortisation and provisions | 2,698 | 2,806 |
| Other expenses | | 153 |
| **Operating profit/(loss)** | **(6,959)** | **(6,204)** |
| **Financial income/(expense)** | **44** | **(243)** |
| **Exceptional income/(expense)** | **(109)** | **35** |
| Corporate tax | 1,150 | 962 |
| **Net profit/(loss)** | **(5,874)** | **(5,450)** |

*The financial statements for the six months to 30 June 2022 were approved by the Management Board on 20 September 2022 and presented at the Supervisory Board meeting of 20 September 2022.*

Operating income totalled €3.4 million in the first half of 2022, an increase of 6%. It includes revenue of €0.45 million representing the first milestone in Crossject's contractual relationship with Eton Pharmaceuticals (corresponding to the completion of a first industrial transposition batch of ZENEO® Hydrocortisone).

Operating expenses were up 10% compared with the first half of 2021, reflecting the final development phases before submission of marketing authorisation applications, which are more costly than the first (launch of the ZENEO® Midazolam clinical study, ZENEO® Hydrocortisone industrial transposition batch, ZENEO® Midazolam human factors study).

In total, the operating loss was €6.9 million (compared with a loss of €6.2 million in the six months to 30 June 2021).

After taking into account net financial income/(expense) and the Research Tax Credit, which was up sharply in line with the strength of R&D activity, net profit/(loss) was a loss of €5.8 million, compared with a loss of €5.4 million in the first half of 2021.

In the first half, Crossject significantly strengthened its equity following the conversion of almost all of its convertible bonds in the amount of €12 million and the exercise of warrants in the amount of €2.4 million. The company's equity was €3.1 million as of 30 June 2022, compared to €5.4 million as of 31 December 2021.

As of 30 June 2022, Crossject had cash and cash equivalents of €5.7 million, compared with €9.9 million as of 31 December 2021. Investments in the final phases of pharmaceutical and industrial development required for the filing of marketing authorisation applications, in particular for ZENEO® Midazolam, are the main causes of the €4.2 million reduction in cash and cash equivalents.

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## About CROSSJECT • www.crossject.com

CROSSJECT (ISIN: FR0011716265; Ticker: ALCJ; LEI: 969500W1VTFNL2D85A65) is developing and is soon to market a portfolio of drugs dedicated to emergency situations: epilepsy, overdose, allergic shock, severe migraine and asthma attack. Thanks to its patented needle-free self-injection system, Crossject aims to become the world leader in self-administered emergency drugs. The company has been listed on the Euronext Growth market in Paris since 2014; it receives funding from both BARDA (Biomedical Advanced Research and Development Authority) in the United States and Bpifrance in France.

# Appendix: Financial statements as of 30 June 2022

| Income statement (in €k) | 30/06/2022 | 30/06/2021 | Change |
|---|---|---|---|
| Revenue | 454 | 412 | 42 |
| Stored production | 137 | 132 | 5 |
| Capitalised production | 2,521 | 2,482 | 39 |
| Subsidies | (4) | 111 | (115) |
| Reversals of provisions and transfers of expenses | 234 | 39 | 195 |
| Other income | 32 | 0 | 32 |
| Operating income | **3,374** | **3,176** | **151** |
| Inventories of purchases | 248 | 245 | 3 |
| Other purchases and external expenses | 3,566 | 2,955 | 611 |
| Taxes and duties | 75 | 104 | (29) |
| Salaries and wages | 2,484 | 2,165 | 319 |
| Social security contributions | 1,144 | 952 | 192 |
| Depreciation and amortisation of fixed assets | 2,698 | 2,388 | 310 |
| Provisions | | 418 | (418) |
| Other expenses | 118 | 153 | (35) |
| Operating expenses | **10,333** | **9,380** | **953** |
| **Operating profit/(loss)** | **(6,959)** | **(6,204)** | **(755)** |
| **Financial income/(expense)** | **44** | **(243)** | **287** |
| **Exceptional income/(expense)** | **(109)** | 35 | **(144)** |
| Income taxes | 1,150 | 962 | 188 |
| **NET PROFIT/(LOSS)** | **(5,874)** | **(5,450)** | **(424)** |

| BALANCE SHEET – ASSETS (in €k) | 30/06/2022 | 31/12/2021 | CHANGE |
|---|---|---|---|
| **FIXED ASSETS** | | | |
| R&D | 9,361 | 9,124 | 237 |
| Patents and trademarks | 1 | 6 | (5) |
| Other intangible assets | 1 | 11 | (10) |
| Land | 89 | 89 | 0 |
| Buildings | 2,839 | 2,930 | (91) |
| Industrial fixtures, plant, machinery and equipment | 1,146 | 1,305 | (159) |
| Other property, plant and equipment | 345 | 396 | (51) |
| Fixed assets in progress | 2,661 | 2,426 | 235 |
| Other equity investments | 76 | 76 | 0 |
| Related receivables | 402 | 310 | 92 |
| Other long-term investments | 391 | 427 | (36) |
| Other financial assets | 12 | 12 | 0 |
| **TOTAL FIXED ASSETS** | **17,324** | **17,112** | **212** |
| **CURRENT ASSETS** | | | |
| Inventories | 853 | 863 | (10) |
| Work in process | 759 | 502 | 257 |
| Advances and prepayments | 344 | 295 | 49 |
| State and other receivables | 2,607 | 2,769 | (162) |
| Investment securities | 181 | 154 | 27 |
| Available cash | 5,589 | 9,829 | (4,240) |
| **TOTAL CURRENT ASSETS** | **10,333** | **14,412** | **(4,070)** |
| **TOTAL ASSETS** | **27,657** | **31,524** | **(3,867)** |

| BALANCE SHEET – LIABILITIES (in €k) | 30/06/2022 | 31/12/2021 | CHANGE |
|---|---|---|---|
| **SHAREHOLDERS' EQUITY** | | | |
| Capital | 3,465 | 2,604 | 861 |
| Share premium | 13,690 | 6,036 | 7,654 |
| Other reserves | 0 | 0 | 0 |
| Retained earnings | (8,785) | (3,980) | (4,805) |
| Investment subsidies | 640 | 665 | (25) |
| Profit/(loss) for the year | (5,875) | (10,805) | 4,930 |
| **TOTAL SHAREHOLDERS' EQUITY** | **3,135** | **(5,480)** | **8,615** |
| Conditional advances | 7,476 | 7,476 | 0 |
| Provisions for contingencies and charges | 751 | 811 | (60) |
| **BORROWINGS AND DEBT** | | | |
| Bonds | 548 | 12,587 | (12,039) |
| Loans | 7,712 | 7,945 | (233) |
| Miscellaneous | 2,668 | 2,794 | (126) |
| Debts – Trade payables | 1,912 | 1,961 | (49) |
| Tax and social security liabilities | 1,325 | 1,117 | 208 |
| Debts on fixed assets | 2,095 | 2,247 | (152) |
| Other liabilities | 35 | 66 | (31) |
| **TOTAL DEBT** | **16,295** | **28,717** | **(12,422)** |
| **TOTAL EQUITY AND LIABILITIES** | **27,657** | **31,524** | **(3,867)** |

| STATEMENT OF CASH FLOWS (in €k) | 30/06/2022 | 31/12/2021 |
|---|---|---|
| **Net profit/(loss)** | **(5,875)** | **(10,806)** |
| Depreciation, amortisation and provisions | 2,370 | 5,078 |
| Gain/(loss) on disposal | 147 | |
| Other income and expenses calculated | (41) | (33) |
| Cash flow from operations | (3,399) | (5,761) |
| Change in working capital requirements | 31 | (328) |
| **(1) Net cash generated by (used in) operating activities** | **(3,368)** | **(6,089)** |
| Acquisition of fixed assets | (2,837) | (6,732) |
| Disposal of fixed assets, net of tax | 30 | |
| **(2) Net cash generated by (used in) investing activities** | **(2,807)** | **(6,732)** |
| Capital increase | 83 | |
| Share premium | 2,392 | |
| Bonds | | 13,066 |
| Subsidies | | 716 |
| Subscription of borrowings | | 369 |
| Repayment of borrowings | (360) | (195) |
| Debts on fixed assets | (152) | (962) |
| Repayable advances | | 1,527 |
| **(3) Net cash generated by (used in) financing activities** | **1,963** | **14,521** |

| | | |
|---|---|---|
| **Change in cash and cash equivalents (1)+(2)+(3)** | **(4,212)** | **1,700** |
| | | |
| **Opening cash position** | **9,983** | **8,277** |
| **Closing cash position** | **5,771** | **9,983** |