

Press release

# 2022 annual results A year of major developments Substantial increase in operating income

Dijon, 20 March 2023, 8.00 p.m.

CROSSJECT (ISIN: FR0011716265; Ticker: ALCJ), a specialty pharma company that is developing and will soon be marketing a portfolio of drugs for use in emergency situations (epilepsy, allergic shock, overdose, asthma attack, adrenal insufficiency, etc.), presents its annual results for 2022.

"In 2022, Crossject experienced a truly unprecedented year in its history. The growth embedded in contracts signed to date offers unique visibility and marks the turning point we have been waiting for. Optimising our resources to support Crossject's ramp-up is now our priority, along the lines of the non-dilutive financing we have implemented. Thanks to the efforts of all our teams and the support of our shareholders, especially Gemmes Venture, a major shareholder from the early days, the Crossject story is only just beginning. The momentum for success is there and our teams are more motivated than ever to make us a key player in the pharma sector. Lastly, I would like to thank our investor and shareholder Vester Finance, which hs managed its bonds with great care in a long-term perspective." Patrick Alexandre – Chairman of the Management Board

With its patented needle-free self-injection system, Crossject aims to become the world leader in self-administered emergency medication. Crossject is a human-sized company working out of two sites (Dijon and Gray) and covering a wide range of activities, from the design/development of medicines to the preparation of their marketing and their manufacture.

After 20 years of research and development, Crossject has achieved major clinical, industrial and commercial milestones in the last two years, laying solid foundations for its future.

#### **Emergency situations**

Crossject specialises in pre-hospital emergencies. Patients diagnosed at risk of life-threatening seizures can get a prescription for their emergency dose from their doctor, fill the prescription in a pharmacy and then carry it with them at all times.

People are generally not in a medical environment when they have seizures, so they either have to inject the emergency dose themselves or have it done by a member of their family, who is not a health professional. That is where our ZENEO® needle-free injector comes in. ZENEO® is pre-filled and single-use, very easy to understand and extremely safe to use. The ergonomics of our system owe much to cooperation with patient associations for several indications, and has been validated by more than 1,000 people in total on countless occasions. In most cases, an injection can be performed in under a minute, even in stressful situations or by someone unfamiliar with ZENEO®. In the latest "human factors" study in the United States (see press release of 12 September 2022), an exceptional proportion of 99.6% of people successfully completed the injection.

In addition, thanks to its ability to inject the dose in less than a tenth of a second (compared with several seconds for most conventional systems), ZENEO® eliminates most of the risks of misuse.



## Efficacy of ZENEO®

ZENEO® has a long history of proven efficacy and flexibility, with more than 10 clinical studies under its belt, including a 2014 bioequivalence study in combination with subcutaneous methotrexate.

However, in most emergency situations, such as epilepsy or allergic shock, it is preferable to administer the drug by intramuscular injection, potentially through clothing. ZENEO® has recently demonstrated its ability to perform such injections (see our press release of 2 November 2022 announcing the positive readout of the ZENEO® Midazolam clinical study, developed for epileptic seizures). This makes Crossject the only company worldwide to offer a means of intramuscular injection (on bare skin or through clothing) in a fraction of a second.

## Crossject, developer of therapeutic solutions

Crossject is a developer of therapeutic solutions, working both on the ZENEO® medical device and on the combination of ZENEO® with a drug adapted to each therapeutic indication.

As a company with ISO 13485 certification for the design, development, production and manufacture of a sterile single-use auto-injector (see our press release of 15 August 2022) and as a pharmaceutical company (see our press release of 16 November 2021), Crossject is ideally positioned to develop innovative solutions.

Marketing authorisation applications for the three priority indications (epilepsy, acute adrenal insufficiency, allergic shock) are scheduled to be submitted in 2024. However, the goal is still to file an Emergency Use Authorization application under the BARDA contract in 2023 (see below).

It is important to note that Crossject used advanced reliability quantification techniques to develop ZENEO® in order to meet the FDA's very demanding standards (at least 99.999% compliant injections, which is equivalent to less than ten mechanical failures per million injections).

#### Crossject, manufacturer

Crossject has a three-stage industrial chain for the manufacture of its medical devices. Upstream, the company subcontracts the manufacture of components to partners with the necessary expertise in plastic or metal injection, glass forming, elastomer moulding, etc. Crossject generally owns the specific tools, which are integrated into the partner's industrial facilities.

Downstream, Crossject sources its active ingredients from specialised chemical manufacturers and delivers them to a manufacturer specialised in the mixing and filling of sterile injectable liquid products (fill/finish). Crossject also supplies the manufacturer with a ready-to-fill kit consisting of two sub-assemblies: a sterile pharmaceutical sub-assembly, intended to receive the drug, prepared and shipped from Crossject's Dijon site, and an actuator (the injector's mechanical part), assembled and shipped from Crossject's Gray site.

Crossject already has highly efficient industrial facilities; each piece of equipment has its own capacity, so the maximum capacity of the whole is determined by the slowest workstation; Crossject accordingly has production capacity of more than 500,000 ready-to-fill kits per year — capacity that is about to increase with the ongoing installation of new equipment recently delivered with the support of France Relance (press release of 10 March 2021).

Crossject's medium-term strategy is to grow its industrial capacity by removing bottlenecks as business needs change. The renovation of a 1000 sq.m. building on the Gray site (delivery scheduled before this summer) will allow Crossject to lift its capacity to more than 6 million units per year.

#### Marketing

Crossject initially chose to entrust the distribution of its products to pharmaceutical companies already established in the relevant geographies and therapeutic indications.

The priority geographies are North America and Western Europe.

Of the seven therapeutic indications in its portfolio, two are already covered by licensing agreements, namely acute adrenal insufficiency for North America (press release of 16 June 2021) and epilepsy for Germany (press release of 18 June 2019), for which several milestones have been successfully achieved.

A new indication could also be developed in partnership with an American laboratory (press release of 15 September 2022).



Crossject's epilepsy product is also the subject of a contract with BARDA (the US government agency that supports the research, development and manufacture of medical products for public health emergencies) (press release of 18 June 2022, contract no. 75A50122C00031). The total value of the contract – if all options are exercised – is \$155 million and includes advanced regulatory development in the United States and the supply of products to the US Strategic National Stockpile, upon approval from the US Food and Drug Administration (FDA). The aim is to start deliveries by the end of 2023, subject to obtaining Emergency Use Authorisation (EUA) from the Food Drug Administration (FDA).

### Crossject, a committed company

In recent years, Crossject has demonstrated its commitment on CSR questions, with a gender equality index reading above 90 for two consecutive years and a significant increase in its GAIA index from 15 to 60 in just three years. The company has also received a Responsible Care® award, demonstrating its commitment to transforming itself into a major player in the field of life-saving emergency medicines.

## Financial information as of 31 December 2022

In line with the business plan, the strengthening of our financial base to support the very substantial acceleration of our development was a real success in 2022. The €22 million financial reinforcement came from several sources;

- BARDA invoicing: \$1.8 million invoiced in 2022
- Free allocation of equity warrants to all shareholders: €2.8 million
- Capital increase with preferential subscription rights: €4.09 million
- Exercise of warrants: €0.2 million
- New borrowings: at the end of the year we completed a major non-dilutive financial transaction of €14 million, with €4 million in loans granted in 2022. The transaction includes various loans granted by long-standing banks (Caisse d'Epargne and BNP), Société Générale and BPI, with amortisation periods ranging from 5 to 10 years, and nearly 85% of the total available immediately.

All OC1223 convertible bonds were converted during the year and 95.7% of the OC1224 convertible bonds were converted during the year, the balance being converted this day.

In the year ended 31 December 2022, we recorded a very substantial increase in operating income to €9.7 million, an increase of 43%.

It includes €0.95 million in revenue relating to milestones achieved during the year.

€ thousand, as of 31 December	2022	2021
Operating income	9,718	6,772
Operating expenses	-23,005	-18,594
Purchases of raw materials and supplies	-498	-954
Other purchases and external expenses	-8,116	-5,901
Personnel expenses	-7,424	-6,183
Taxes and duties	-176	-202
Depreciation, amortisation and provisions	-6,358	-5,013
Other expenses	-433	-342
Operating profit/(loss)	-13,288	-11,823
Financial income/(expense)	-319	-774
Exceptional income/(expense)	228	81
Corporate tax	2,222	1,818
Net profit/(loss)	-11,157	-10,698

The financial statements for the six months to 31 December 2022 were approved by the members of the Management Board on 20 March 2023 and presented at the Supervisory Board meeting of 20 March 2023. They have been audited.



In addition, capitalised production increased by 13% to  $\epsilon$ 6.1 million as a result of ongoing research and development activities.

During the year, Crossject maintained its focus on cost control. Operating expenses increased by just 24%, a very moderate rise in relation to that of operating income.

Other purchases and external expenses amounted to  $\in 8.1$  million, compared with  $\in 5.9$  million in 2021, attributable notably to the progress of production work linked to the BARDA contract, the completion of various clinical studies and batches on several drugs in the portfolio and the costs inherent to the industrial ramp-up in the broad sense.

At the end of 2022, Crossject had approximately 100 employees, a slight increase compared with the end of 2021. Personnel expenses amounted to €7.4 million in 2022, compared with €6.2 million in 2021, taking into account recruitments in 2022 aimed at obtaining more qualified skills better suited to our stage of development.

The overall operating loss was €13.3 million, compared with a loss of €11.8 million in 2021.

The Group recorded net financial expense of 0.3 million for 2022, compared with an expense of €0.9 million for 2021.

After taking into account exceptional income of €0.2 million and a Research Tax Credit of €2.2 million, an increase of €0.4 million on 2021, the net loss for 2022 was €11.2 million.

As of 31 December 2022, Crossject had cash of €8 million (€10 million at the end of 2021), plus €6.2 million in non-dilutive financing announced at the end of the year and €3.8 million from the same plan, yet to be received, of which €2.0 million is conditional on obtaining Emergency Use Authorisation (EUA) from the Food Drug Administration (FDA).

In view of current contracts (and in particular monthly invoicing to BARDA) and the very clear visibility Crossject has acquired in recent months, the company is confident in its ability to find the necessary financing to continue its development.

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# About CROSSJECT • www.crossject.com

Crossject (ISIN: FRoo11716265; 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, and benefits from Bpifrance funding.



# **APPENDICES**

Income statement (in €k)	44561	44561	Change
Revenue	954	912	42
Stored production	348	170	178
Capitalised production	6	5,383	-5,377
Subsidies	5	185	-180
Reversals of provisions and transfers of expenses	445	98	347
Other income	1,861	24	1,837
Operating income	3,619	6,772	-3,153
Purchases of raw materials and other supplies	1,002	1,143	-141
Change in inventory (raw materials and other supplies)	-505	-189	-316
Other purchases and external expenses	8,115	5,901	2,214
Taxes and duties	177	202	-25
Personnel expenses	7,425	6,183	1,242
Depreciation, amortisation	5,263	4,490	773
Other provisions	1,095	523	572
Other expenses	433	342	91
Operating expenses	23,005	18,595	4,410
Operating profit/(loss)	-19,386	-11,823	-7,563
Financial income/(expense)	-319	-882	563
Exceptional income/(expense)	228	81	147
Research Tax Credit	2,222	1,818	404
NET PROFIT/(LOSS)	-17,255	-10,806	-6,449



BALANCE SHEET – ASSETS (in €k)	31/12/2022	31/12/2021	CHANGE
FIXED ASSETS			
R&D	10,691	9123	1,568
Patents and trademarks		6	-6
Other intangible assets		11	-11
Land	89	89	0
Property, plant and equipment	5,085	4,631	454
Assets under construction	2,492	2,426	66
Financial assets	672	516	156
TOTAL FIXED ASSETS	19,029	16,802	2,227
CURRENT ASSETS			
Raw materials, other supplies	1,416	863	553
Work in process	588	503	85
Advances and prepayments received on orders in progress	345	294	51
Trade and related receivables	726	44	682
State and other receivables	2,450	1,931	519
Marketable securities		154	-154
Available cash	7,769	9,830	-2,061
Prepaid/deferred expenses	536	923	-387
TOTAL CURRENT ASSETS	13,830	14,542	-712
TOTAL ASSETS	32,859	31,344	1,515



BALANCE SHEET – LIABILITIES (in €k)	31/12/2022	31/12/2021	CHANGE
SHAREHOLDERS' EQUITY			
Capital	3652	2604	1048
Share premium	18312	6036	12276
Regulated reserve	0	0	0
Retained earnings	-8786	-3980	-4806
Profit/(loss) for the year	-11157	-10698	-459
Investment subsidies	665	665	0
TOTAL SHAREHOLDERS' EQUITY	2686	-5373	8059
Conditional advances	7476	7476	0
Provisions for contingencies and charges	1420	810	610
BORROWINGS AND DEBT		•	-
Bonds	355	12587	-12232
Loans	11048	7946	3102
Miscellaneous	2722	2794	-72
Debts – Trade payables	3523	1961	1562
Total tax and social security liabilities	1833	1183	650
Debts on fixed assets	1764	2247	-483
Deferred income	32	0	32
TOTAL DEBT	21277	28718	-7441
TOTAL EQUITY AND LIABILITIES	32859	31631	1228



HEADINGS	31/12/2022	31/12/2021
Net profit/(loss)	- 11,157.00	- 10,806.00
Depreciation, amortisation and provisions	5,705.00	5,078.00
Capital gains on disposal, net of tax	1,00	
Other income and expenses calculated	- 28.39	- 28.39
Cancellation of exceptional income on cancellation of debt		
Cash flow from operations	-5,479.39	- 5 756,39
Change in working capital requirements	399.03	- 327,32
(1) Net cash generated by (used in) operating activities	-5,080.36	- 6,083.71
Acquisition of fixed assets	-6,778.69	- 6,732.62
(2) Net cash generated by (used in) investing activities	-6,778.69	- 6,732,62
Capital increase	4,088.86	
Exercise of warrants	3,003.17	
Bonds	-	13 066.09
Loans	4,000,00	- 6,123.84
Repayment of borrowings	- 969.15	7,826.09
Subsidies	-	716,13
Debts on fixed assets	- 483.21	- 962,18
Repayable advances		_
(3) Net cash generated by (used in) financing activities	9,639.67	14,522.30
Change in cash and cash equivalents (1)+(2)+(3)	-2,219.38	1,705.97
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Opening cash position	9,983.07	8,277.11
Closing cash position	7,769.58	9,983.07