

## 2020 annual results and business update

- Continued development: final stretch for two priority products
- First effects of the ramp-up of commercial presence in the USA
- Securing of industrial facilities
- Financial structure strengthened and adapted to 2021 funding needs

Dijon, 29 March 2021

**CROSSJECT (ISIN: FR0011716265; Ticker: ALCJ), a specialty pharma company developing and soon marketing a portfolio of drug / device combinations for use in emergency situations, is announcing its 2020 results and issuing a business update.**

Patrick Alexandre, Crossject CEO, said: *“In 2020, Crossject continued to grow despite the consequences of the health crisis, thanks to the unwavering commitment of its employees – and I thank them wholeheartedly. Production resumed very quickly after the first period of lockdown, we opened a subsidiary in the United States to ramp up our commercial presence in that country, and we continued work to secure and consolidate our industrial facilities. Last December’s round of fundraising of €12 million, combined with the €1.5 million in aid granted under the stimulus plan, allows us to approach 2021 with confidence. We plan to focus our efforts on preparing the items contained in our MA<sup>1</sup> applications and continuing to increase our industrial capacity in preparation for future drug launches. During his visit to Gray in February 2021, Bruno Le Maire, Minister for the Economy, Finance and Recovery, praised the ‘high technology’ of ZENEO® and its ‘high value added’, describing it as ‘fascinating’ and ‘revolutionary’. This recognition touched all Crossject teams, who are proud to contribute to the development of life-saving medicines.”*

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<sup>1</sup> MA: marketing authorisation



## Update on activity in 2020 and early 2021

### *Continued development of the portfolio*

Committed to a high level of quality, in keeping with both its own ambitions and the regulatory requirements of the FDA<sup>2</sup> – success rate of over 99.999% for each injection – and the European authorities, Crossject has launched the manufacture of an additional batch before the start of the clinical bioequivalence study for ZENEO® Midazolam and the manufacture of the last development batches (validation batches). The clinical study, for which Crossject has obtained all necessary approvals, is due to be carried out this year. The advances on ZENEO® Midazolam benefit the entire portfolio, as the process is largely replicable for each ZENEO® drug. As a reminder, each ZENEO®/drug combination requires, for each proposed dosage, the manufacture of 5 to 6 batches representative of commercial production in order to provide the information needed for a marketing authorisation file: validation of manufacturing processes, stability of the drug, clinical programme, etc.

At the same time, production has started for the ZENEO® Epinephrine<sup>3</sup> batches. Two batches (one adult and one child dose) are being produced. In addition, stability tests conducted since the release of the new ZENEO® Epinephrine formulation in March 2020<sup>4</sup> have consistently confirmed the superiority of the patented formulation. A longer period of stability than other drugs is an additional advantage for ZENEO® Epinephrine in the existing market.

In line with its regulatory strategy, Crossject has submitted its ZENEO® Epinephrine development plan to the European Medicines Agency (EMA) and is currently in discussion with the FDA.

Alongside these advances on ZENEO® Midazolam and ZENEO® Epinephrine, Crossject is continuing its work on its other drugs so that the first batches can be produced quickly as progress is made on the commercial side.

### *Business development: stronger presence for Crossject in the United States in 2020*

An increasing number of confidentiality agreements were signed with potential US customers in the final quarter of 2020, following the appointment of a Vice-President US Business of the newly created US subsidiary in September.

Discussions and negotiations currently underway concern not only ZENEO® Midazolam and ZENEO® Epinephrine, but also several other products in the portfolio. All teams are working to complete the due diligence audits accompanying these discussions.

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<sup>2</sup> FDA: Food and Drug Administration

<sup>3</sup> Epinephrine is the name used in the US for Adrenaline

<sup>4</sup> See press release dated 20 March 2020



At the same time, discussions continue with US federal authorities, even though the decision-making process has been slowed by the pandemic, which is mobilising the Department of Defense and BARDA<sup>5</sup> and prompting both to prioritise Covid-19 vaccination and treatments. BARDA announced in June and October 2020 its intention to solicit proposals to replace diazepam auto-injectors in the CHEMPACK programme with Midazolam auto-injectors. Although the request for proposals has not been issued to date, Crossject believes that it will have many strong points to put forward. As a reminder, Midazolam is a molecule that stops epileptic seizures and can also be used as an emergency treatment in the event of nerve agent attacks.

### ***Crossject: from R&D company to industrial company***

In 2020, Crossject produced nearly 15,000 ZENEO® units. In addition to the production of these units, the teams were mobilized and structured to support the increase in industrial capacity, which is now sufficient for regulatory developments and the first commercial launches. Accordingly, Crossject's production facilities are currently capable of producing commercial-sized batches of up to 500,000 units per year.

Crossject is also continuing work to consolidate and secure its industrial facilities: dual sourcing of the main components, duplication of existing equipment, and shift work on certain workstations at the Gray site.

The €1.5 million grant awarded as part of France's stimulus plan will fund part of the €7.5 million industrial investment plan to be implemented between 2021 and 2022. This investment plan is aimed notably at making the industrial facilities more robust to meet prospective variations in demand or possible technical incidents. The infrastructure in place will increase Crossject's visibility among business partners. In the longer term, infrastructure will gradually be expanded to bring production capacity to 6 million units per year.

In addition, alongside these internal industrial processes, Crossject is adapting all of its supply contracts in order to shift from an R&D approach to mass production, with a view to securing prices and quality.

Finally, the resolute ISO 13485 certification process continues. Audits began in December 2020 and to date represent more than 15 person days (auditors). Their purpose is to certify the compliance and soundness of the Quality System rolled out across all of the company's activities. The strength of the Quality System is already acknowledged, and the production of the next batches of ZENEO® Midazolam will finalise the process. Although not mandatory, certification is an additional asset aimed at reassuring future customers and authorities as to the compliance of the entire production system with quality and safety requirements.

### ***Crossject: a committed company***

As its underlying ambition is to save lives, Crossject is naturally committed to acting responsibly in respect

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<sup>5</sup> Biomedical Advanced Research and Development Authority



of its employees and society as a whole.

In 2019, Crossject decided to increase the non-financial information in its documentation to highlight the first aspects of its approach. This resulted in a significant improvement in the Gaia rating published in 2020, particularly in the employer category, underlining the company's commitment to its employees. The gender equality index also demonstrates this commitment, with a score of 84/100 in 2020 – the same as the previous year, despite the complex environment stemming from the pandemic. In addition, Crossject has signed the Responsible Care® charter put forward by France Chimie and was awarded a prize by the Conseil Régional de Bourgogne-Franche-Comté in the Fair Trade Practices category.

In 2021, Crossject plans to roll out an action plan to strengthen its commitment and initiatives in all areas of CSR.

## **Covid-19 update**

Crossject demonstrated agility by taking a series of measures and implementing tools in the interests of its employees and the company. Telework made it possible to carry out a large number of activities under optimal conditions during lockdown. Today, telework remains in place for activities that allow it. The protection of teams that have to work on site remains a priority.

Although the level of uncertainty related to the Covid-19 crisis remains high and Crossject cannot yet commit to a timetable for the submission of marketing authorisation applications, the company does not foresee any major difficulties in continuing its operations. The strategy of favouring partners and suppliers as close as possible to the company's geographical location is proving its effectiveness. The Group will disclose the prospective timing as soon as the situation has stabilized.

## **Outlook**

Crossject intends to pursue the execution of its roadmap to achieve its goals in term of industrial rollout, regulatory advances, and the signing of new partnerships in the United States and Europe:

- Produce the ZENEO® units needed for MA applications,
- Carry out a clinical bioequivalence study in 2021 for at least one product in the portfolio, prioritising ZENEO® Midazolam,
- Respond to BARDA's potential request for proposals, which, if it was issued in the first half of 2021 and if Crossject was selected, could result in first sales of ZENEO® Midazolam during the second half of 2022,
- Sign new commercial agreements, prioritizing North America.

## Financial information as of 31 December 2020

€thousand, as of 31 December	2020	2019
<b>Operating income</b>	<b>5,731</b>	<b>5,994</b>
<b>Operating expenses</b>	<b>(16,403)</b>	<b>(14,637)</b>
Purchases of raw materials and supplies	(986)	0
Other purchases and external expenses	(4,885)	(6,391)
Personnel expenses	(5,328)	(4,307)
Taxes and duties	(201)	(142)
Depreciation, amortisation and provisions	(4,556)	(3,797)
Other expenses	(447)	0
<b>Operating profit/(loss)</b>	<b>(10,672)</b>	<b>(8,643)</b>
<b>Financial income/(expense)</b>	<b>(250)</b>	<b>110</b>
<b>Exceptional income/(expense)</b>	<b>(568)</b>	<b>23</b>
Corporate tax	1,646	1,336
<b>Net profit/(loss)</b>	<b>(9,844)</b>	<b>(7,174)</b>

The financial statements for the year ended 31 December 2020 were approved by the Management Board on 24 March 2021 and presented at the Supervisory Board meeting of 26 March 2021. The auditors' report is pending. In 2020, Crossject recognised expenses previously reported under "Other purchases and external expenses" under "Purchases of raw materials and supplies" and "Other expenses". In 2019, these expenses amounted to €837 thousand and €592 thousand respectively.

Despite the health context, Crossject's operating income held up well during the year, reflecting control of external expenses, although the number of employees increased in line with the company's stage of development.

In the year ended 31 December 2020, operating income amounted to €5.7 million, a slight decline of 4% reflecting an unfavourable comparison base related to the DESITIN agreement and the renegotiation of the ZENEO® Epinephrine contract, which generated €0.5 million in revenue and €1.5 million in other income respectively in 2019. The relative stability of operating income in 2020 is attributable chiefly to the increase in capitalised production (€4.6 million, vs €3.9 million in 2019) in line with the progress of the development of the drug portfolio.

Operating expenses increased by €1.8 million from €4.6 million to €6.4 million as the company continued to develop and structure itself. As of 31 December 2020, Crossject had 94 employees, an increase of nearly 20% year on year. Despite the health crisis and telework, Crossject continued to recruit, mainly for production and industrial functions, in line with the company's stage of development.

Overall, the result of operations for the year ended 31 December 2020 was a loss of €10.7 million, an increase of €2.0 million in the loss year on year.

Net financial income/(expense) deteriorated by €0.4 million, bearing in mind the funding obtained in October 2019. In addition, Crossject recorded net exceptional expenses linked to the provision for a dispute

in the amount of €0.5 million, for which the company has lodged an appeal. After taking into account these items and an increase in the Research Tax Credit (€1.6 million, vs €1.3 million in 2019), the net loss was €0.8 million (€7.2 million in 2019).

As of 31 December 2020, Crossject had cash and cash equivalents of €8.2 million, compared with €7.9 million as of 31 December 2019. Over the year, the company benefited from a €6 million government-guaranteed loan and a €5.2 million convertible bond cashed in December, which strengthened its financial position in the context of its development (negative cash flow from operations of €5.0 million) and investments in the industrial process (€6.1 million used in investing activities).

In addition, the following cash contributions were secured in 2021:

- €5.2 million bond issue, to be cashed in April 2021 (press release of 14 December 2020);
- €3 million in public funding announced on 14 December, which has been received (€1 million paid by Bpifrance under the PIAVE programme) or is in the process of being received;
- Payment of half of the €1.5 million subsidy allocated under the stimulus plan (press release of 19 February 2021).

Together, these past and future contributions secure the bulk of Crossject's cash flow requirements for the coming year. They could also be supplemented by other public aid, as applications are currently being prepared, and by resources resulting from the contribution of commercial contracts (existing and under discussion). Always mindful of the consolidation of its equity and cash flow, the company has decided to transform the ordinary bonds issued at the end of 2020 into convertible bonds at the time of the payment of the funds scheduled for April 2021, as set out below. This transaction will return the Group to positive equity.

## **Issuance of convertible bonds subscribed by offsetting receivables**

To consolidate its equity pending future commercial contracts, the company has decided, with the agreement of the bondholders, to transform the ordinary bonds issued at the end of 2020 in the amount of €5.2 million into convertible bonds (OC1223) at the time of the payment of the funds scheduled for April 2021. The 5,402,063 new convertible bonds, the issue of which was authorised by the Supervisory Board at its meeting of 26 March 2021 and adopted by the Management Board on the same day, will have the same characteristics and will be fungible with the convertible bonds issued in December 2020.<sup>[2]</sup>

As an indication, if all convertible bonds were converted, including those issued in December and still outstanding, i.e. a total of 6,599,729 convertible bonds, on the basis of Crossject's closing share price on 26 March 2021,<sup>[4]</sup> a shareholder holding 1% of Crossject's capital before conversion would see his or her stake reduced to 0.926% of the capital on an undiluted basis<sup>[5]</sup> (and 0.905% of the capital on a diluted basis,

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<sup>[2]</sup> See press release dated 14 December 2020

<sup>[4]</sup> 3.35 euros

<sup>[5]</sup> Based on share capital comprising 25,304,427 shares as of 26 March 2021



taking into account existing dilutive instruments<sup>[6]</sup>).

## Risk factors

Investors should refer to the risk factors described in the 2019 Annual Financial Report and the 2020 Half-Yearly Financial Report available on the company's website: [www.crossject.com](http://www.crossject.com).

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## About CROSSJECT • [www.crossject.com](http://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, and benefits from Bpifrance funding.

Translation for information purposes only. In case of discrepancy between the French and English versions of this press release, only the French version should be deemed valid.

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<sup>[6]</sup> Including 631,939 potential shares linked to existing dilutive instruments

## Appendix: Financial statements for the year ended 31 December 2020

Income statement (in €k)	31/12/2020	31/12/2019	Change
Revenue	0	500	-500
Stored production	683	23	660
Capitalised production	4,624	3,921	703
Subsidies	220	481	-261
Reversals of provisions and transfers of expenses	184	68	115
Other income	20	1,000	-980
<b>Operating income</b>	<b>5,731</b>	<b>5,994</b>	<b>-263</b>
Purchases of raw materials and other supplies	904	0	904
Change in inventory (raw materials and other supplies)	81	0	81
Other purchases and external expenses	4,885	6,391	-1,506
Taxes and duties	201	142	59
Personnel expenses	5,328	4,307	1,021
Depreciation, amortisation	3,949	3,647	302
Other provisions	607	150	457
Other expenses	447	0	447
<b>Operating expenses</b>	<b>16,403</b>	<b>14,637</b>	<b>1,766</b>
<b>Operating profit/(loss)</b>	<b>-10,672</b>	<b>-8,643</b>	<b>-2,029</b>
<b>Financial income/(expense)</b>	<b>-250</b>	<b>110</b>	<b>-360</b>
<b>Exceptional income/(expense)</b>	<b>-567</b>	<b>23</b>	<b>-590</b>
Employee profit-sharing	1	0	1
Research Tax Credit	-1,646	-1,336	-310
<b>NET PROFIT/(LOSS)</b>	<b>-9,843</b>	<b>-7,174</b>	<b>-2,669</b>

STATEMENT OF CASH FLOWS (in €k)	30/06/2020	31/12/2019
<b>Net profit/(loss)</b>	<b>-9,844</b>	<b>-7,174</b>
Depreciation, amortisation and provisions	4,897	3,631
Other income and expenses calculated	-33	-275
Cash flow from operations	-4,980	-3,817
Change in working capital requirements	(482)	-1,695
<b>(1) Net cash generated by (used in) operating activities</b>	<b>(5,462)</b>	<b>-5,510</b>
Acquisition of fixed assets	(6,096)	-4,401
Disposal of fixed assets, net of tax		
<b>(2) Net cash generated by (used in) investing activities</b>	<b>-6,096</b>	<b>-4,401</b>
Redemption of convertible bonds	-80	
Bonds	5,240	5,378
Exercise of warrants		3,155
Subscription of borrowings	6,000	3,700
Repayment of borrowings	-135	
Debts on fixed assets	695	-100
Repayable advances	210	543
<b>(3) Net cash generated by (used in) financing activities</b>	<b>11,930</b>	<b>12,998</b>
<b>Change in cash and cash equivalents (1)+(2)+(3)</b>	<b>373</b>	<b>3,087</b>
<b>Opening cash position</b>	<b>7,905</b>	<b>4,819</b>
<b>Closing cash position</b>	<b>7,269</b>	<b>7,906</b>

BALANCE SHEET – ASSETS (in €k)	31/12/2020	31/12/2019	CHANGE
<b>FIXED ASSETS</b>			
R&D	7,528	6,220	1,307
Patents and trademarks	0	0	0
Other intangible assets	9	33	-24
Land	75	75	0
Property, plant and equipment	5,093	5,702	-609
Assets under construction	1,587	0	1,587
Financial assets	615	491	124
<b>TOTAL ASSETS</b>	<b>14,907</b>	<b>12,522</b>	<b>2,385</b>
<b>CURRENT ASSETS</b>			
Raw materials, other supplies	917	0	917
Work in process	608	1,454	-846
Advances and prepayments	267	0	267
State and other receivables	8,086	2,090	5,996
Marketable securities	144	103	41
Available cash	8,133	7,802	331
Prepaid/deferred expenses	528	524	4
<b>TOTAL CURRENT ASSETS</b>	<b>18,683</b>	<b>11,973</b>	<b>6,710</b>
<b>TOTAL ASSETS</b>	<b>33,590</b>	<b>24,495</b>	<b>9,096</b>

<b>BALANCE SHEET – LIABILITIES (in €k)</b>	<b>31/12/2020</b>	<b>31/12/2019</b>	<b>CHANGE</b>
<b>SHAREHOLDERS' EQUITY</b>			
Capital	2,388	2,020	368
Share premium	7,212	1,880	5,332
Regulated reserve	0	6,288	-6,288
Retained earnings	-886	0	-886
Profit/(loss) for the year	-9,844	-7,174	-2,670
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>-1,130</b>	<b>3,014</b>	<b>-4,144</b>
Conditional advances	5,949	5,739	210
Provisions for contingencies and charges	806	182	624
<b>BORROWINGS AND DEBT</b>			
Bonds	10,498	5,799	4,700
Loans	7,956	2,100	5,856
Miscellaneous	2,611	2,600	11
Debts – Trade payables	2,355	1,915	440
Tax and social security liabilities	1,227	633	594
Debts on fixed assets	3,209	2,514	695
Deferred income	109	0	109
<b>TOTAL DEBT</b>	<b>27,966</b>	<b>15,560</b>	<b>12,406</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>33,590</b>	<b>24,495</b>	<b>9,096</b>