

2019 annual results and business update

- Operational facilities resolutely preparing for large series
- Gradual focus on the United States
- Reduction of losses, thanks in large part to commercial activities
- Covid-19 likely to have an impact on timing, but teams remain operational

Dijon, 26 March 2020

CROSSJECT (ISIN: FR0011716265; Ticker: ALCJ), a specialty pharma company that is developing and will soon be marketing a portfolio of combined drugs for use in emergency situations, is announcing its 2019 results and issuing a business update.

Patrick Alexandre, CEO of Crossject, said: *"2019 was a bumper year for the company. The contract signed with Desitin Pharma and the R&D cooperation agreement with the United States Department of Defense demonstrate the value of our products and our technology, and that is something we are proud of. Today, our industrial facilities are able to produce ZENEO® devices, from components to the finished product. In the coming year, we will continue our efforts to prepare our supply chain for a ramp-up of production, while remaining vigilant about its robustness and regulatory compliance at every stage of the process. We are also counting on the conclusion of new commercial agreements given the quality of our products, which we continue to improve, such as ZENEO® Adrenaline and its new medicinal formulation. The progress made in 2019 is the result of the combined efforts of all our teams and the support of our shareholders. I thank them all. In the context marked by the Covid-19 epidemic, our priority is to protect our employees and preserve our operational achievements. At the moment, it is still too early to measure the impact the epidemic will have on our business, but we all remain committed to our shared ambition: make Crossject the leader in emergency drugs."*

Update on activity since the start of 2020

Industrial advances: operational facilities resolutely preparing for large series

In 2019, Crossject continued its efforts to improve and secure its industrial facilities ready for large-scale production. An inspection of our manufacturer by the Belgian authorities during the production of a batch of ZENEO® Naloxone served to confirm that all production lines are approved for the manufacture



of the clinical batches necessary for MA¹ dossiers. Crossject also continued its capex policy in 2019: its automated tube washing by integrating it into the PARC[®] production module, and implemented an integrated management software package (ERP) to streamline the supply chain. Moreover, the company has improved quality procedures applying both to suppliers and internally at all stages of production. It has also invested in securing its supply for the most critical components (double sourcing and duplication of certain production facilities) and pharmaceutical raw materials (multi-year inventory policy).

Crossject is also on track for ISO 13485 certification. The results of the mock audit carried out in 2019 and the receipt of pharmaceutical establishment status demonstrate the pertinence of Crossject's quality approach.

Continued development of the drug portfolio

Crossject is actively pursuing the development of its drug portfolio with a view to filing its first MA dossiers.

In 2019, a "human factors" study was carried out in America, giving very good results. 146 volunteers placed in the conditions of a life-threatening emergency tested ZENEO[®] Midazolam, ZENEO[®] Adrenaline, ZENEO[®] Terbutaline and ZENEO[®] Naloxone. 87% successfully completed all stages until injection. Of the 99 volunteers questioned following their use of ZENEO[®], 94% agreed that the system's general use did not pose problems for them, with 36% describing it as "easy" and 45% as "very easy".

The industrial transfer (adaptation and qualification of production methods defined in the laboratory on industrial lines) for ZENEO[®] Naloxone and ZENEO[®] Midazolam has been the subject of intense activity, involving close work with our manufacturing partner. The stability data of the batches produced (in particular the 12-month data concerning Midazolam), are in line with our expectations.

ZENEO[®] Midazolam: significant advances in 2019

In 2019, ZENEO[®] Midazolam chalked up significant advances confirming the drug's appeal and potential.

First, Crossject signed a commercial agreement on ZENEO[®] Midazolam in Germany with Desitin Pharma, leader in the field of epilepsy in Germany. The agreement concerns licensing, distribution and promotion for a period of 10 years from commercial launch, unless either Crossject or Desitin opts to exercise certain withdrawal clauses, for instance if minimum sales are not reached or if certain milestones are not respected. Desitin paid Crossject €0.5 million on signing. It will pay €0.5 million on a development milestone expected in 2020, then €0.5 million on an additional development milestone expected within 12 months, plus a further €1 million when the MA is obtained. Crossject will sell the product to Desitin at a percentage of the net selling price applied by Desitin to wholesalers, in the mid-double digits and with

¹ Marketing authorisation



a floor unit price.

Second, the company has signed a research and development cooperation agreement with the United States Department of Defense (DoD). Benzodiazepine auto-injection systems are currently the gold-standard treatment for victims of attack with a nerve agent.

The interest shown by several federal agencies is a real opportunity to reposition ZENEO[®] Midazolam in America, despite the “orphan drug” exclusivity previously granted in the indication of Status Epilepticus to another injectable midazolam product presented in an ampoule for injection with a needle. To that end, Crossject consulted the FDA² about ZENEO[®] Midazolam at the end of the year.

ZENEO[®] Adrenaline: enhanced commercial potential

On 20 March 2020, Crossject announced two major advances for ZENEO[®] Adrenaline.

As recently explained,³ the 2019 patent application for a new formulation of ZENEO[®] Adrenaline, an emergency treatment against anaphylactic shock (allergic reaction), was the subject of a favourable report by the INPI⁴ on all patentability criteria. On one hand it does not contain sulphites, the drug solution is not allergenic; at the same time, its shelf life should be longer than that of the products currently on the market. On top of that, the volume of active ingredient remaining in the device after use is minute in comparison with other self-injection systems.

Crossject has also announced that it has repurchased the marketing and development rights for ZENEO[®] Adrenaline. The transaction holds out the prospect of the signing of new licensing agreements with higher upfront payments, thanks to the new formulation and the maturity of the development of the ZENEO[®] platform.

ZENEO[®] Naloxone: a promising market, currently on hold

In 2019, Crossject had discussions with the FDA on the development of ZENEO[®] Naloxone. Faced with the mounting number of deaths from the use of opioid painkillers, the United States is seeking emergency treatment for overdoses. ZENEO[®] Naloxone responds perfectly to emergency situations like those.

However, given recent news concerning large laboratories accused of having inappropriately promoted opioid-based painkillers, and which could be forced to distribute Naloxone rescue kits at their expense, Crossject is taking the time to analyse the situation and opportunities in the light of ongoing developments.

ZENEO[®] Methotrexate: recovery of commercial rights for France

² Food and Drug Administration

³ See press release dated 20 March 2020

⁴ French National Industrial Property Institute (*Institut National de la Propriété Industrielle*)



By mutual agreement, the partnership signed in July 2012 between Crossject and Biodim for ZENEO[®] Methotrexate has been terminated in France. Biodim has been acquired by Neuraxpharm, a laboratory specialising in neurology, and which has no marketing activity in the segment of rheumatoid arthritis, the condition treated by ZENEO[®] Methotrexate. The amicable termination does not entail the reimbursement by Crossject of the €250,000 paid by Biodim when the contract was signed. Crossject once again holds the rights to ZENEO[®] Methotrexate in France.

Business development: continuation of commercial efforts

In 2019, Crossject continued its business development efforts, which resulted in the conclusion of the commercial agreement with Desitin Pharma on ZENEO[®] Midazolam in Germany and the cooperation agreement with the DoD. The team is fully committed to continuing its efforts based on the good newsflow on ZENEO[®] Adrenaline and the prospects for ZENEO[®] Midazolam (see above).

In addition, the Crossject Supervisory Board has authorised the Management Board to create a legal entity in the United States in order to be able to employ personnel there, notably in business development.

Covid-19 information and outlook

Crossject is making every effort to ensure the safety of its employees and limit the impact of the epidemic on its activity.

From the start of the epidemic, measures were taken to protect employees whose activity requires their physical presence on the Gray and Dijon production sites. Telework has been adopted for all activities that allow it, with most employees having the means necessary to continue their activities thanks to our anticipations upstream.

Given the magnitude and uncertain duration of the Covid-19 epidemic, it is too early to accurately assess its impact on Crossject's business. However, the suspension of certain activities will have consequences on the timing of submission of the first MA dossiers. The production of the first two clinical batches, well advanced before the government lockdown measures, has had to be suspended. It will not resume until they have been lifted. Crossject has already decided to prioritise the development of ZENEO[®] Midazolam under the agreement with Desitin and the pursuit of discussions with the American federal authorities interested in the product, in order to cement progress. To date, bi-weekly updates with the DoD have not been disturbed by the unfolding epidemic.

Crossject will continue development work on its other priority products, reserving the possibility of reviewing the prioritisation of its portfolio based on commercial progress.

Note that there is no risk of supply disruption for our customers, since Crossject's products are still in the development phase.

Crossject's cash position increased to €7.9 million at the end of 2019. The company has taken measures to limit its expenses and postpone non-priority spending. It is also studying all of the various possibilities announced recently by the government to address the crisis.

Financial information as of 31 December 2019

€ thousand, as of 31 December	2019	2018
Operating income	5,994	3,524
Operating expenses	(14,637)	(15,081)
Other purchases and external expenses	(6,391)	(7,659)
Personnel expenses	(4,307)	(3,972)
Taxes and duties	(142)	(126)
Depreciation, amortisation and provisions	(3,797)	(3,324)
Operating profit/(loss)	(8,643)	(11,557)
Financial income/(expense)	110	(737)
Exceptional income/(expense)	22	(10)
Income tax	1,336	1,592
Net profit/(loss)	(7,174)	(10,712)

The financial statements for the year ended 31 December 2019 were approved by the Management Board at its meeting of 24 March 2020 and presented at the Supervisory Board meeting of 24 March 2020. The auditors' report is pending.

Operating income totalled €6.0 million in 2019, an increase of €2.5 million. Crossject generated revenue of €0.5 million during the year, with the first upfront provided for by the marketing agreement with Desitin. Capitalised production rose from €2.4 million at the end of 2018 to €3.9 million at the end of 2019. Crossject also recognised €1 million in connection with the renegotiation of the ZENEO® Adrenaline contract (see press release dated 20 March 2020).

Operating expenses were stable at €14.6 million, compared with €15.1 million in 2018, reflecting the company's good control of expenses in a context of development and continued hiring. As of 31 December 2019, the company had 77 employees, compared with 75 at the end of 2018.

2019 operating income was a negative €8.6 million (negative €11.6 million in 2018). The net loss totalled €7.1 million (loss of €10.7 million in 2018).

As of 31 December 2019, Crossject had a higher amount of cash and cash equivalents of €7.9 million, compared with €4.8 million at the end of 2018. As a reminder, Crossject supplemented its funding with various cash contributions in 2019:

- upfront payment of €0.5 million,



- structured financing of €2.6 million,
- proceeds of €3.2 million from the exercise of warrants,
- public funding, with €1.9 million received in the second half (CIR, PIAVE, DGA, Europe, VAT, etc.),
- issue of €5.7 million in convertible bonds.

Crossject anticipates additional cash flows in 2020 in the form of aid under contract and commercial income from existing or new licensing agreements. These amounts will enable the company to fund its priority developments in 2019. In addition, Crossject is continuing its efforts to strengthen its long-term financing.

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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, and benefits from Bpifrance funding.

Appendix: Financial statements for the six months to 31 December 2019

Income statement (in €k)	Dec-19	Dec-18	Change
Revenue	507		507
Stored production	23	645	-622
Capitalised production	3921	2423	1,498
Operating subsidies	481	21	460
Reversals of depreciation, amortisation and provisions, transfer of expenses	61	435	-374
Other income	1,000		1,000
Total operating income	5,993	3,524	2,469
Inventories of purchases			0
Other purchases and external expenses	6,391	7,658	-1,267
Taxes, duties and similar payments	142	126	16
Wages and salaries	2,973	2,729	244
Social security contributions	1,334	1,244	90
Depreciation and amortisation of fixed assets	3,647	2,968	679
Provisions	149	355	-206
Other expenses			0
Total operating expenses	14,636	15,080	-444
OPERATING PROFIT/(LOSS)	-8,643	-11,556	2,913
FINANCIAL INCOME/(EXPENSE)	110	-737	847
RECURRING INCOME BEFORE TAX	-8,533	-12,293	3,760
EXCEPTIONAL INCOME/(EXPENSE)	23	-10	33
Income taxes	1,336	1,592	-256
NET PROFIT/(LOSS)	-7,174	-10,711	3,537

Balance sheet – Assets (in €k)	31-Dec-19			Dec-18	Change
	Gross	Depreciation	Net		

Fixed assets

Research and development	16,031	9,810	6,221	4,615	1,606
Concessions, patents, similar rights	20,429	20,429	0	0	0
Other intangible assets	185	152	33	36	-3
Land	75		75	75	0
Buildings	3,699	547	3,152	3,326	-174
Industrial plant, machinery and equipment	6,378	4,211	2,167	2,577	-410
Other property, plant and equipment	789	406	383	363	20
Assets under construction					
Other equity investments	100		100	100	0
Other long-term investments	1,562	1,217	345	180	165
Other financial assets	46		46	55	-9
Sub-total	49,294	36,772	12,522	11,327	1,195

Current assets

Inventories	1,870	416	1,454	1,523	-69
Advances and prepayments on orders				159	-159
Trade and other receivables	5		5		5
Other receivables	2,085		2,085	1,826	259
Investment securities	103		103	59	44
Available cash	7,802		7,802	4,760	3,042
Prepaid expenses	324		324	225	99
Sub-total	12,189	416	11,773	8,552	3,221
Deferred expenses	200		200	280	-80
Total	61,683	37,188	24,495	20,159	4,336

Balance sheet – Liabilities (in €k)	Jan-19	Dec-18	Change
Shareholders' equity			
Share capital	2,020	13,603	-11,583
Share, merger, contribution premiums, etc.	1,880	1,895	-15
Regulated reserves	6,288		6,288
Retained earnings		-3,132	3,132
Profit/(loss) for the year	-7,174	-10,711	3,537
Sub-total	3,014	1,655	1,359
Conditional advances	5,195	5,195	0
Provisions for contingencies and charges			
Provisions for contingencies			
Provisions for charges	182	125	57
Sub-total	182	125	57
Borrowings and debt			
Bonds	5,799	5,475	324
Bank loans and debts	2,100	1,000	1,100
Loans and various borrowings	543		543
Advances and down-payments received on orders in progress	2,600	1,000	1,600
Trade and other payables	1,915	2,568	-653
Tax and social security payments	629	526	103
Debts on fixed assets	2,514	2,614	-100
Other liabilities	4	1	3
Sub-total	16,104	13,184	2,920
Total	24,495	20,159	4,336