

Annual 2018 results and business update

- First clinical batches in the spring
- Confirmation of the schedule of marketing authorisation filings
- Signing of licensing agreements planned for 2019
- New business opportunities in the US for ZENEO® Naloxone and ZENEO® Midazolam

Dijon, 13 March 2019

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 2018 results and issuing a business update.

Patrick Alexandre, CEO of Crossject, said: *“2018 was an eventful year, with the ramp-up of our industrial organisation. Crossject is now able to produce 500,000 units a year. The decision to insource certain key production lines, combined with a more robust quality control strategy, is finally paying off. In early 2019, the grant of pharmaceutical establishment status rewarded our efforts in terms of Quality and Regulatory Compliance. Last December, our shareholders and new investors helped us raise €4 million, demonstrating their strong support for our plans. On the strength of these advances and encouraged by the latest developments, which are potentially very favourable for the marketing of ZENEO® Naloxone and ZENEO® Midazolam in the United States, our teams are all working hard to achieve our 2019 objectives: signing of licensing agreements, production of clinical batches and launch of bioequivalence studies.”*



Business update

Production of clinical batches set to start in the spring: confirmation of the MA filing schedule

Testing and checks on the quality of the ZENEO® component, whose production resumed last November, have given full satisfaction. The complex mould, which has been completely renovated, produces very good quality components. Crossject is carrying out the final audits before starting to produce clinical batches in the spring. They will be used for bioequivalence studies, starting from 2019.

At the same time, the preparation of dossiers to file for MA¹ is progressing, with the aim of filing the first requests in the United States and Europe in 2020, in priority for ZENEO® Naloxone, ZENEO® Midazolam² and ZENEO® Adrenaline.

Lastly, the pertinence of Crossject's pharmaceutical development strategy is reflected in the interest shown by the European and American regulatory agencies, with which the company has had around 20 consultations, nine of which in the last two years.

Licensing agreements set to be signed in 2019

Discussions with potential partners are continuing in Europe and the United States. Crossject confirms its aim of signing licensing agreements in 2019. The company is seeing an increase in interest in ZENEO® medicines, as indicated by the number of non-disclosure agreements signed with US companies, five times more in 2018 than in 2015. Non-disclosure agreements are signed after initial talks and mark the beginning of in-depth discussions.

The momentum in commercial discussions can be attributed to advances in drug development, particularly ZENEO® Naloxone, an emergency treatment for opioid overdose, where the number of victims is increasing every year, particularly in the United States.

ZENEO® Naloxone: broader perspectives

In view of the epidemic of opioid overdose, the FDA³ is seeking to develop emergency

¹ MA: Marketing authorisation issued by the relevant regulatory authorities

² Filing in Europe

³ FDA: Food and Drug Administration



treatments⁴. Two major developments could emerge quickly:

- A co-prescription that would allow the routine prescription of a Naloxone emergency kit for each prescription of opioid-based medicines. The FDA estimates the need at 48.5 million doses per year.
- The possibility of allowing patients to buy a Naloxone antidote in a pharmacy, over the counter (OTC).

These two potential regulatory developments are expected to significantly expand the prospects for ZENEO® Naloxone.

ZENEO® Midazolam: the US back in the sights

Crossject is currently finalising a development strategy for ZENEO® Midazolam (indication, clinical programme, etc.), developed with a panel of leading American epileptologists. It is free of risk of interference with existing orphan indications. Several potential partners are interested.

Gradual preparation of ZENEO® for commercial scale production

In January 2019, Crossject seized the operational and financial opportunity to lease a surface area of 1,000 sq.m near its Gray plant. The additional area will allow the company to gradually duplicate, and as such secure, production lines dedicated to the actuator, an integral part of the ZENEO® device. In this way, Crossject is giving itself the means to gradually duplicate its production facilities to keep up with market demand once MAs are granted.

Pharmaceutical establishment status: acknowledgement of the Quality approach

In early 2019, Crossject obtained the authorisation to open a pharmaceutical establishment⁵. By granting this status, the ANSM⁶ authorises Crossject to release clinical batches and perform quality controls on finished products for human use in its own laboratory. The status acknowledges the Quality strategy implemented to support Crossject's development. It also helps build credibility and increase the company's visibility with potential partners.

⁴ <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM629048.pdf>

⁵ See press release dated 30 January 2019

⁶ ANSM: French National Agency for the Safety of Medicines and Health Products



Cash contributions since 31 December 2018

In December 2018, Crossject raised €4 million through a capital increase with maintenance of preferential subscription rights, bringing its cash balance to €4.8 million at the end of 2018.

In January 2019, the company received a further cash injection via a €1.1 million loan granted jointly by Bpifrance (the French public investment bank) and the Bourgogne-Franche-Comté region. This loan is spread over a period of eight years, with a grace period of three years.

Crossject expects to receive additional cash contributions in 2019:

- As announced previously⁷, in the form of already agreed aid, plus the research tax credit – which together represent more than €3 million – plus commercial revenues from licensing agreements. These contributions will enable Crossject to fund its priority developments in 2019.
- And in the form of other aid – currently under preparation or development – and non-dilutive contributions currently under discussion. Crossject is continuing its efforts to strengthen its long-term financing.

Free allocation of equity warrants to all shareholders in 2019

Crossject announced its intention to grant free equity warrants to its shareholders to thank them for their support and loyalty. The company intends to put a resolution to this effect to the vote of its shareholders at the Combined General Meeting scheduled for 20 June 2019. The exercise of the warrants will subsequently provide cash to the company.

⁷ See press release dated 27 November 2018

Financial information as of 31 December 2018

Income statement as of 31 December 2018

€ thousand, as of 31 December	2018	2017
Operating income	3,524	4,142
Operating expenses	(15,080)	(12,763)
Other purchases and external expenses	(7,659)	(7,371)
Personnel expenses	(3,972)	(3,059)
Taxes and duties	(126)	(59)
Depreciation, amortisation and provisions	(3,324)	(2,274)
Operating profit/(loss)	(11,556)	(8,621)
Financial income/(expense)	(737)	159
Exceptional income/(expense)	(10)	(278)
Income tax	1,592	1,129
Net profit/(loss)	(10,711)	(7,611)

The unaudited financial statements for the year ended 31 December 2018 were approved by the Management Board on 12 March 2019 and presented at the Supervisory Board meeting on the same day.

The 2018 results reflect progress in the company's developments in line with the MA filing schedule in 2020 and the contained impact of the production incident that occurred during the year.

Operating income accordingly amounted to €3.5 million, down compared with 2017 due to the production issues in the second half. The increase in "Other purchases and external expenses" reflects Crossject's tight rein on expenses in a context of development. The company had 75 employees at the end of 2018, compared with 58 at the end of 2017. Hiring was mainly focused on Quality, Maintenance, Production and Supply Chain positions, in line with the needs of the company at this stage of its development. Personnel expenses increased in line with hirings during the year.

After taking into account financial expense, impacted chiefly by the impairment of treasury shares and the research tax credit of €1.6 million for the year, the net loss was €10.7 million.

The gross value of inventories increased over the year (additional €0.6 million in gross value), illustrating the company's further development and explaining most of the increase in the working capital requirement (€1.0 million). Capex totalled €3.3 million (€4.2 million in 2017). Net cash from



financing activities totalled €13.3 million (€9.4 million in 2017), benefiting from the capital increase and the convertible bonds issue. Overall, Crossject's cash position was up year on year at the end of 2018: €4.8m in cash and cash equivalents, compared with €2.6m at the end of 2017.

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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.

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.

Appendix: Annual financial statements 2018

Income statement (in €k)	Dec-18	Dec-17	Change
Revenue			
Stored production	645	804	-159
Capitalised production	2,423	2,983	-560
Operating subsidies	21	251	-230
Reversals of depreciation, amortisation and provisions, transfer of expenses	435	104	331
Other income			0
Total operating income	3,524	4,142	-459
Inventories of purchases			0
Other purchases and external expenses	7,658	7,371	287
Taxes, duties and similar payments	126	59	67
Wages and salaries	2,729	2,123	606
Social security contributions	1,244	936	308
Depreciation and amortisation of fixed assets	2,968	2,256	712
Provisions	355	18	337
Other expenses			0
Total operating expenses	15,080	12,763	2,317
OPERATING PROFIT/(LOSS)	-11,556	-8,621	-2,935
FINANCIAL INCOME/(EXPENSE)	-737	159	-896
RECURRING INCOME BEFORE TAX	-12,293	-8,462	-3,831
EXCEPTIONAL INCOME/(EXPENSE)	-10	-278	268
Income taxes	1,592	1,129	463
NET PROFIT/(LOSS)	-10,711	-7,611	-3,100

Balance sheet – Assets (in €k)	Dec-18			Dec-17	Change
	Gross	Depreciation	Net		
Fixed assets					
Research and development	12,110	7,495	4,615	4,031	584
Concessions, patents, similar rights	20,429	20,429	0	0	0
Other intangible assets	155	119	36	26	10
Land	75		75	75	0
Buildings	3,699	373	3,326	3,500	-174
Industrial plant, machinery and equipment	6,006	3,429	2,577	1,896	681
Other property, plant and equipment	701	338	363	294	69
Assets under construction			0	754	-754
Other equity investments	100		100	100	0
Other long-term investments	1,562	1,382	180	694	-514
Other financial assets	55		55	48	7
Sub-total	44,892	33,565	11,327	11,418	-91
Current assets					
Inventories	1,847	324	1,523	1,201	322
Advances and prepayments on orders	160		160	0	160
Other receivables	2,330		2,330	2,291	39
Investment securities	59		59	165	-106
Available cash	4,760		4,760	2,641	2,119
Sub-total	9,156	324	8,832	6,298	2,534
Total	54,048	33,889	20,159	17,716	2,443

Balance sheet – Liabilities (in €k)	Dec-18	Dec-17	Change
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Shareholders' equity

Share capital	13,603	8,958	4,645
Share, merger, contribution premiums, etc.	1,895	27,691	-25,796
Other reserves	0	40	-40
Retained earnings	-3,132	-22,993	19,861
Profit/(loss) for the year	-10,711	-7,611	-3,100
Sub-total	1,655	6,085	-4,430

Conditional advances	5,195	3,747	1,448
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Provisions for contingencies and charges

Provisions for contingencies	0	1	-1
Provisions for charges	125	93	32
Sub-total	125	94	31

Borrowings and debt

Bonds	5,475		5,475
Bank loans and debts	1,000	1,000	0
Advances and down-payments received on orders in progress	1,000	1,000	0
Trade and other payables	2,568	2,628	-60
Tax and social security payments	526	645	-119
Debts on fixed assets	2,614	2,514	100
Other liabilities	1	3	-2
Sub-total	13,184	7,790	5,394
Total	20,159	17,716	2,443

Cash flow statement (in €k)	31/12/2018	31/12/2017
Net profit/(loss)	-10,711	-7,611
Depreciation, amortisation and provisions	3,838	2,054
Capital gains on disposal, net of tax		
Other comprehensive income and expenses	-120	
Cancellation of exceptional income on cancellation of debt		
Cash flow from operations	-6,993	-5,557
Change in working capital requirements	-1,024	583
(1) Net cash generated by (used in) operating activities	-8,017	-4,974
Acquisition of fixed assets	-3,273	-4,248
Disposal of fixed assets, net of tax		
(2) Net cash generated by (used in) investing activities	-3,273	-4,248
Capital increase	3,414	1,667
Share premium	591	5,745
Bond	7,750	
Commercial paper		-755
Debts on fixed assets	100	-720
Repayable advances	1,448	3,457
(3) Net cash generated by (used in) financing activities	13,303	9,394
Change in cash and cash equivalents (1)+(2)+(3)	2,013	172
Opening cash position	2,806	2,634
Closing cash position	4,819	2,806

