

# Annual 2017 results and business update

- A milestone in 2017: start-up of the manufacturing unit
- 2017 recurring income before taxes stabilised at -€8.5 million
- Cash position as of end-2017: €2.8 million; €8 million of additional cash expected by the end of 2018, of which €5.2 million already received
- Confirmation of the schedule of marketing authorisation filings

Dijon, 20 March 2018

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 annual 2017 results and providing a business update.

#### Patrick Alexandre, CEO of Crossject, said:

"2017 was a defining year for Crossject. The company continued to develop its drug portfolio with the integration of ZENEO® Terbutaline, in-sourced major elements of the production chain and built up its organisation. Today, Crossject is able to produce drugs in industrial conditions, a major step in its development.

The beginning of 2018 was marked by fresh progress: orphan drug designation from the FDA for ZENEO® Midazolam, publication of the Intuitive study and strengthening of the financial structure. Crossject will also receive a repayable state subsidy that will help go towards financing the development of the Gray site: we are proud to be receiving this support, which acknowledges our ability to forge ahead on the industrial side of our business.

Crossject plans to continue implementing its strategy and strengthening its production capacity as its project develops. All teams are focused on our goal of becoming the world's leading pharmaceutical laboratory for self-injected emergency products."



#### **Business update**

## Production lines now operational: a major achievement in the industrial and regulatory process

Crossject is now able to produce ZENEO® devices on an industrial scale. The PARC® production line has been making the sterile ready-to-fill tubes since the end of 2017, while the gas generator production line has been operational since the beginning of 2018. With production capacity now firmly in place, the company has taken a major step towards the production of batches of combined products (ZENEO® filled with drugs) necessary for the filing of MA applications.¹ In the second half of 2017, the PARC® production unit delivered 20,000 sterile glass tubes to CENEXI, Crossject's partner in charge of filling the tubes. The pace of production accelerated in early 2018: a further 20,000 units will have been produced and delivered by the end of March.

At the same time, Crossject is finalising the documentary qualification procedure for its production lines, another key step prior to the production of clinical batches.

Crossject will continue to progressively expand its production capacity to support the increase in product volumes required for the regulatory process.

#### Confirmation of the schedule of marketing authorisation filings

Thus, Crossject confirms its MA application filing schedule in the United States and Europe (2019 for ZENEO® Sumatriptan, ZENEO® Midazolam, ZENEO® Adrenaline, ZENEO® Hydrocortisone and ZENEO® Naloxone; 2020 for ZENEO® Methotrexate and ZENEO® Terbutaline).

#### Orphan drug designation obtained from the FDA for ZENEO® Midazolam

By granting orphan drug designation to ZENEO® Midazolam for Status Epilepticus in the United States in February 2018, the Food and Drug Administration (FDA) allowed Crossject to reach another milestone. This designation confirms the pertinence of Crossject's strategic focus of prioritising emergency drugs in its portfolio.

#### Intuitive study and Janus prize: validation of ZENEO®'s ergonomics

The ergonomics and ease of use of ZENEO® were highlighted by the *Intuitive* study: 93% of healthy volunteers successfully handled ZENEO®, 97% believe that ZENEO® is easy to use, 99% would ask their doctor to prescribe ZENEO® instead of another injector. The study, published in early March 2018, was conducted with 134 people in 2017. Each subject used ZENEO® with a user's manual and without external help.

This came on top of the award of the "Janus de la perspective" label of excellence for ZENEO®'s design and ergonomics granted in November 2017.

ZENEO®'s intuitiveness and ease of use, combined with its ability to inject a dose of medication in less than 50 ms, are the features that give ZENEO® its unique positioning in emergency situations outside hospitals.

<sup>&</sup>lt;sup>1</sup> MA: Marketing authorisation issued by the relevant regulatory authorities.



#### Commercial negotiations

The FDA's decision to grant orphan drug designation to ZENEO® Midazolam increases Crossject's international visibility and provides support for the tender offer launched last December in the search for a partner to market the drug in the United States.

At the same time, Crossject is continuing commercial negotiations for a licensing agreement for ZENEO® Sumatriptan in the United States in the first half of 2018.

#### Cash contributions early 2018

On 12 February 2018, Crossject announced the issue of €5.3 million in convertible bonds, accompanied by the free allotment of warrants. These transactions enhance the company's development capacity.

In addition, the French state granted Crossject repayable funding of €500 thousand as part of the "Growth and Development" incentive. The funding is repayable after two years, and will serve to finance the increase in the capacity of the Gray site and, by extension, the company's industrial facilities.

#### Financial information as of 31 December 2017

The company continued its structural development with a view to becoming a pharmaceutical laboratory specialising in self-administered emergency drugs, with, in particular, operational production lines and the hiring of 23 people supervised by an experienced operational management team.

#### Financial information as of 31 December 2017

Income statement as of 31 December 2017

Income statement € thousand, as of 31 December	2017	2016
Operating income	4,142	1,427
Operating expenses	(12,763)	(8,718)
Other purchases and external expenses	(7,371)	(4,494)
Personnel expenses	(3,059)	(2,380)
Taxes and duties	(59)	(71)
Depreciation and amortisation	(2,274)	(1,773)
Operating profit/(loss)	(8,621)	(7,291)
Financial income/(expense)	159	(1,059)
Exceptional income/(expense)	(278)	592
Income tax	1,129	1,095
Net income	(7,611)	(6,663)

The financial statements for the year ended 31 December 2017 were approved by the Management Board on 13 March 2018 and presented at the Supervisory Board meeting of 19 March 2018. The financial statements have been audited. The auditors' report is currently being issued.



Operating revenue amounted to  $\leq$ 4,142 thousand in the year ended 31 December 2017, compared with  $\leq$ 1,427 thousand in the year ended 31 December 2016. This increase reflects the ramp-up of the industrial facilities and production over the year. As such, stored production related to the continued constitution of the stocks necessary to make registration batches increased strongly (by  $\leq$ 1,167 thousand). Capitalised production also increased (by  $\leq$ 1,673 thousand).

Operating expenses amounted to €12,763 thousand, compared with €8,718 in 2016, again highlighting the acceleration of the company's development. Other purchases and external expenses increased in line with the stock of components required for production. Personnel expenses were impacted by the increase in the number of employees from 39 to 58 over the period, which served to build up qualified teams and allowed the in-sourcing of the skills needed for Crossject's development. Recruitments have helped strengthen production skills, but also quality control and medical functions, in connection with the world of healthcare.

The net financial income of €159 thousand in 2017 resulted primarily from a reversal of provisions on treasury shares. The previous financial year included an impairment of €1,043 thousand on treasury shares.

On the basis of the preceding items, recurring income before tax was a loss of €8,462 thousand, a level almost identical to that of the previous year, which saw a loss of €8,350 thousand.

In 2017, Crossject recorded an exceptional loss of €278 thousand, including a net exceptional expense of €153 thousand related to the increase in the volume of securities allocated to the liquidity contract and deducted from the stock of treasury shares.

In total, after taking into account tax revenue (€1.13 million from the Research Tax Credit, compared with €1.1 million in 2016), the company's net result was a loss of €7,611 thousand, compared with a loss of €6,663 thousand in 2016.

Crossject has been able to contain the cash burn generated by its operations, which totalled €4,974 thousand in 2017, compared with €4,404 thousand in 2016. During this year marked by the ramp-up the industrial facilities, Crossject increased its capital expenditure from €2,291 thousand in 2016 to €4,248 thousand in 2017. After taking into account cash flows from financing activities (€9,394 thousand), relating chiefly to the capital increase in the first half of the year, the cash position stood at €2,806 thousand as of 31 December 2017, compared with €2,634 thousand at the end of 2016.

In 2018, Crossject will be able to rely on additional cash of nearly €8 million, of which €5.3 million already received following the issue of convertible bonds in February 2018. The residual contributions correspond to various aids or subsidies (research tax credit, RAPID, PIAVE). The new cash of €8 million does not include the payment of the €500 thousand financing described above, the payment of which will be staggered over time, potential upfronts negotiated under licensing agreements, the exercise of warrants or new calls for funding. These various cash contributions will provide Crossject with the resources to continue its development in 2018.

As of 31 December 2017, the amount of shareholders' equity after appropriation of income was stable at €6.1 million, compared with €6.3 million as of 31 December 2016.



#### Next release:

16 May 2018 (after trading): Business update

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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, severe migraine, allergic shock, overdose, asthma attack, etc. 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 has notably received financing from Bpifrance.

#### Disclaimer

This press release may contain forward-looking information. This information is based either on trends or objectives, and should not be taken as a forecast of future performance or any other performance indicator. This information is inherently subject to risks and uncertainties, which may in certain cases be beyond the company's control, particularly in the context of an R&D process. A more detailed description of these risks and uncertainties can be found in the company's annual financial report, which is available on its website (<a href="https://www.crossject.com">www.crossject.com</a>).

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: Financial statements for the year ended 31 December 2017**

Dec-17	Dec-16	Change
804	-362	1,166
2983	1310	1,673
251	112	139
104	316	-212
	51	-51
4,142	1,427	1,549
		0
7,371	4,494	2,877
59	71	-12
2,123	1,672	451
936	708	228
2,256	1,705	551
18	68	-50
		0
12,763	8,718	4,045
-8,621	-7,291	-1,330
159	-1059	1,218
-8,462	-8,350	-112
-278	592	-870
		T
1129	1095	34
_7 G11	-6 662	-948
-7,011	-0,003	-948
	804 2983 251 104  4,142  7,371 59 2,123 936 2,256 18  12,763  -8,621  159  -8,462	804 -362 2983 1310 251 112 104 316 51 4,142 1,427  7,371 4,494 59 71 2,123 1,672 936 708 2,256 1,705 18 68  12,763 8,718  -8,621 -7,291  159 -1059  -8,462 -8,350



Balance sheet – Assets (€k)	31-Dec-17			D = 40	Oh - · · ·
	Gross	Depreciation	Net	Dec-16	Change
Fixed assets					
Research and development	9,686	5,655	4,031	2,500	1,531
Concessions, patents, similar rights	20,420	20,420	0		0
Other intangible assets	120	94	26	6	20
Land	75		75	75	0
Buildings	3,699	199	3,500	3,674	-174
Industrial plant, machinery and equipment	4,567	2,671	1,896	1,888	8
Other property, plant and equipment	580	286	294	148	146
Assets under construction	754		754		754
Other equity investments	100		100	100	0
Other long-term investments	1,562	868	694	810	-116
Other financial assets	48		48	52	-4
Sub-total	41,611	30,193	11,418	9,253	2,165
Current assets Inventories	1,201		1,201	398	803
Advances and payments on orders	1,=01		-,		0
Other receivables	2,291		2,291	1,965	326
Marketable securities	165		165	43	122
Available cash	2,641		2,641	2,591	50
Sub-total	6,298		6,298	4,997	1,301
		<u> </u>		1	<u> </u>
Total	47,909	30,193	17,716	14,250	3,466



Balance sheet – Liabilities (€k)		31-Dec-17	Dec-16	Change
Shareholders' equity				
Share capital (of which paid up: 6,650)	8,958	8,958	7,291	1,667
Share, merger, contribution premiums, etc.	27,691	27,691	21,946	5,745
Other reserves	40	40	40	0
Retained earnings	-22,993	-22,993	-16,331	-6,662
Profit/(loss) for the year	-7,611	-7,611	-6,662	-949
Sub-total Sub-total	6,085	6,085	6,284	-199
Conditional advances	4,747	4,747	1,290	3,457
Provisions for contingencies and charges		-		-
Provisions for contingencies	1	1	45	-44
Provisions for charges	93	93	75	18
Sub-total Sub-total	94	94	120	-26
Loans and borrowings				
Bank loans and borrowings		0	755	-755
Advances and down-payments received on orders in progress	1,000	1,000	1,000	0
Trade and other payables	2,628	2,628	1,157	1,471
Tax and social security payments	645	645	409	236
Debts on fixed assets	2,514	2,514	3,234	-720
Other liabilities	3	3	1	2
Sub-total	6,790	6,790	6,556	989
Total	17,716	17,716	14,250	4,221



Net income		
	-7,611	-6,663
Depreciation, amortisation and provisions	2,054	2,511
Capital gains on disposal, net of tax		
Other comprehensive income and expenses Cancellation of exceptional income on cancellation of debt		
Cash flow from operations	-5,557	-4,152
Change in working capital requirements	583	-252
(1) Net cash generated by (used in) operating activities	-4,974	-4,404
Acquisition of fixed assets	-4,248	-2,291
Acquisition of a building		-3,774
(2) Net cash generated by (used in) investing activities	-4,248	-6,065
Capital increase	1,667	640
Share premium	5,745	3,508
Warrants		1
Repayment of borrowings		-188
Commercial paper	-755	755
Debts on fixed assets	-720	3234
Refundable advances	3,457	
(3) Net cash generated by (used in) financing activities	9,394	7,950
Change in cash and cash equivalents (1)+(2)+(3)	172	-2,519
Opening cash position	2 (24	E 153
	2,634	5,153