

Interim 2017 results and business update

- Ramp-up of industrial capacity underway, with some adjustments to ensure GMP compliance
- Impacts on the provisional schedule: delay of approximately 6 months for priority US filings
- Confirmation of the aim of negotiating licensing agreements in 2017
- Reinforcement in emergency products: introduction of Zeneo® Terbutaline (acute asthma attack) into the portfolio
- Cash position as of end-June 2017: €6.1 million, as expected; further contributions of €5.9 million are anticipated by the end of 2018 (excluding commercial upfronts)

Dijon, 21 September 2017

CROSSJECT (ISIN: FR0011716265; Ticker: ALCJ), a specialty pharma company developing a portfolio of innovative combined drugs for use in emergency situations, announces its results for the first half of 2017 and issues a business update.

Patrick Alexandre, Chairman of the Management Board of Crossject, said:

“Crossject continues to implement its strategic priorities: development of innovative drugs based on Zeneo® technology, deployment of production capacity and commercial negotiations. We welcome the quality of our cooperation with Cenexi. However, the running-in phase of our own production capacity has revealed the need to reinforce reliability in some aspects. These issues, inherent to innovative industrial processes, will admittedly have an impact on our schedule, but they do not undermine our determination to bring our projects to fruition. In addition, in agreement with Bpifrance within the PIAVE programme, Crossject has reinforced its positioning in life-saving medicines by introducing Zeneo® Terbutaline into its portfolio. Acute asthma attack is potentially serious and fairly widespread. Zeneo® Terbutaline can provide a solution in these life-threatening emergencies.”

Business update

Positioning of Zeneo® Terbutaline in the priority-development drug pipeline

Given particularly compelling prospects and in agreement with Bpifrance, Crossject has decided to introduce Zeneo® Terbutaline into its portfolio of medicines, thereby reinforcing its strategic positioning on drugs dedicated to life-threatening emergencies. Asthma affects 235 million people worldwide, and each year results in 383,000 premature deaths according to the WHO.¹ About 10% of asthmatics are diagnosed as severe.² A fraction of them are prescribed emergency treatment in the event of a life-threatening emergency, such as an inhalation chamber or a nebuliser, with, for example, the administration of Terbutaline.

In agreement with Bpifrance, Zeneo® Terbutaline is replacing Zeneo® Apomorphine (Parkinson's disease) in the PIAVE funding. Zeneo® Apomorphine nevertheless remains in the portfolio; it will be developed in a second phase without requiring additional resources in the short term.

Progress on industrial production and development, and updated schedule

Industrialisation

The Cenexi Fast Track line has progressed as planned. But anomalies appeared during production in industrial conditions at Crossject's PARC® production plant (ready-to-fill tubes) in Dijon, requiring adjustments to be made. Crossject has taken the necessary measures to remedy the situation, and plans to qualify its industrial facilities by the end of 2017, which will in turn delay the production of clinical and registration batches until early 2018.

Development

In the course of consultations with the regulatory authorities on clinical developments for the various products, it became apparent that the authorities have integrated the advantage of the use of Zeneo® by patients or their entourage as close as possible to the attack. Crossject therefore plans to modify part of the design of comparative bioavailability studies so as to incorporate "human factor" demonstrations into the proper self-administration of Zeneo® drugs by non-physicians.

Clinical studies for Zeneo® Sumatriptan (severe migraine), Zeneo® Adrenaline (anaphylactic shock) and Zeneo® Midazolam (epilepsy) should be ran in 2018.

US marketing authorisation³ filings have been delayed by six months, and filings in Europe and the US are now synchronised in 2019 (Zeneo® Sumatriptan, Zeneo® Midazolam, Zeneo® Adrenaline, Zeneo® Hydrocortisone, Zeneo® Naloxone) and 2020 (Zeneo® Methotrexate and Zeneo® Terbutaline). Crossject confirms and reinforces its strategic priorities announced in November 2016 to primarily target the US market, generating potentially significant commercial upfronts.

¹ <http://www.who.int/mediacentre/factsheets/fs307/en/> accessed 19/9/2017

² The prevalence of severe refractory asthma, The American Academy of Allergy Asthma and Immunology, <https://www.aaaai.org/global/latest-research-summaries/New-Research-from-JACI-In-Practice/refractory-asthma> accessed 19/9/2017

³ Authorisation to market a drug issued by the relevant regulatory authorities.

Commercial negotiations

Crossject confirms its aim of negotiating exclusive licensing agreements in the United States for Zeneo® Sumatriptan and launching a tendering process for Zeneo® Midazolam by the end of 2017.

Financial information for the six months to 30 June 2017

Income statement for the six months to 30 June 2017

Income statement € thousand, as of 30 June	2017	2016
Operating revenue	1,635	1,600
Operating expenses	(5,891)	(4,379)
Other purchases and external expenses	(3,277)	(2,504)
Personnel expenses	(1,343)	(952)
Taxes and duties	(22)	(30)
Depreciation, amortisation and provisions	(1,249)	(893)
Operating income	(4,256)	(2,779)
Financial income/(expense)	396	(518)
Exceptional income/(expense)	(1)	(5)
Income tax	(501)	(471)
Net profit	(3,360)	(2,831)

The financial statements for the six months to 30 June 2017 were approved by the Management Board on 18 September 2017 and presented at the Supervisory Board meeting of 20 September 2017. They are unaudited.

Operating revenue amounted to €1,635 thousand in the six months to 30 June 2017, compared with €1,600 thousand in the six months to 30 June 2016.

Operating expenses amounted to €5,891 thousand (€4,379 thousand in H1 2016).

After a year devoted to strengthening pharmaceutical and commercial teams in 2016, Crossject is focusing on its production team in 2017. Personnel expenses amounted to €1,343 thousand in the first half. Hiring will continue in the second half.

During the first half of 2017, Crossject used consultants to set up the PARC® production unit and procured the necessary components to start production, which resulted in an increase in other purchases and external expenses (+30.9% to €3,277 thousand).

Taking into account these factors, operating income was a negative €4,256 thousand in the six months to 30 June 2017 (negative €2,779 thousand in H1 2016).

Financial income amounted to €396 thousand (expense of €518 thousand in H1 2016), due to the value adjustment of treasury shares.

Net income for the first half was a negative €3,360 thousand (negative €2,831 thousand in H1 2016).

As of 30 June 2017, cash and cash equivalents amounted to €6,096 thousand, compared with €2,634 thousand as of 31 December 2016. During the first half, the company benefited from the March 2017 capital increase (€4,985 thousand) and the payment of repayable advances as part of the Bpifrance's PIAVE financing (€2,820 thousand). The company increased its capex (€1,720 thousand), notably to develop its production capacities, the contribution of which will be accretive in the long term.

Crossject will be able to rely on additional cash estimated at €5.9 million until 31 December 2018. Cash contributions will come from varied sources, including loans, grants, repayable grants, the research tax credit, and the balance of the equity line programme. This amount does not include amounts paid upfront on signature of exclusive distribution agreements, nor treasury shares.

Next release:

Thursday 7 December (after trading): Business update

Contacts:

Crossject

Patrick Alexandre
info@crossject.com

Investor relations

CM-CIC Market Solutions

Catherine Couanau +33 (0) 1 53 48 81 97
catherine.couanau@cmcic.fr

Press relations

Buzz & Compagnie

Mélanie Voisard +33 (0)3 80 43 54 89
melanie.voisard@buzzetcompagnie.com
Audrey Lachat +33 (0)3 80 43 54 89
audrey.lachat@buzzetcompagnie.com

About CROSSJECT • www.crossject.com

Crossject (ISIN: FR0011716265; Ticker: ALCJ) is a specialty pharma company developing a portfolio of drugs for use in emergency situations (severe migraines, epilepsy, temporary paralysis, anaphylactic shock, overdoses, acute asthma attacks, etc.). With Zeneo®, its patented needle-free injection system, Crossject provides an efficient response to emergencies by enabling the simple self-administration of drugs. Crossject has been listed on the Euronext Growth market since February 2014.

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 (www.crossject.com).

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 six months to 30 June 2017

Balance sheet – Assets

Balance sheet – Assets	30-Jun-17			Dec.-16	Chg.
	Gross	Depr.	Net		
Fixed assets					
Research and development	7,356	4,800	2,556	2,500	56
Concessions, patents, similar rights	20,428	20,428	0		0
Other intangible assets	109	86	23	6	17
Land	75		75	75	0
Industrial plant, machinery and equipment	8,213	2,490	5,723	5,561	162
Other property, plant and equipment	574	270	304	148	156
Assets under construction	334		334		334
Other equity investments	100		100	100	0
Other long-term investments	1,855	654	1,201	810	391
Other financial assets	48		48	52	-4
Sub-total	39,092	28,728	10,364	9,252	1,112
Current assets					
Inventories	1,124	239	885	398	487
Advances and payments on orders					0
Other receivables	2,886		2,886	1,965	921
Marketable securities	48		48	43	5
Available cash	6,049		6,049	2,591	3,458
Sub-total	10,107		9,868	4,997	4,871
Total	49,199	28,728	20,232	14,249	5,983

Balance sheet – Liabilities

Balance sheet – Liabilities (in €k)	June-17	June-17	Dec-16	Change
Shareholders' equity				
Share capital (of which paid up: 6,650)	8,814	8,814	7,291	1,523
Share, merger, contribution premiums, etc.	27,226	27,226	21,946	5,280
Other reserves	40	40	40	0
Retained earnings	-22,993	-22,993	-16,331	-6,662
Profit/(loss) for the year	-3,360	-3,360	-6,662	3,302
Sub-total	9,727	9,727	6,284	3,443
Conditional advances	3,847	3,847	1,290	2,557
Provisions for contingencies and charges				
Provisions for contingencies	45	45	45	0
Provisions for charges	86	86	75	11
Sub-total	131	131	120	11
Borrowings and debt				
Bank borrowings and debts		0	755	-755
Advances and down-payments received on orders in progress	1,000	1,000	1,000	0
Trade and other payables	1,770	1,770	1,157	613
Tax and social security payments	522	522	408	114
Debts on fixed assets	3,234	3,234	3,234	0
Other liabilities	1	1	1	0
Sub-total	6,527	6,527	6,555	727
Total	20,232	20,232	14,249	6,738

Income statement

Income statement (in €k)	June-17	June-16	Change
Revenue			
Stored production	728	201	527
Capitalised production	653	617	36
Operating subsidies	234	109	125
Reversals of depreciation, amortisation and provisions, transfer of expenses	20	10	10
Other income		663	-663
Total operating revenue	1,635	1,600	-492
Inventories of purchases			0
Other purchases and external expenses	3,277	2,504	773
Taxes, duties and similar payments	22	30	-8
Wages and salaries	906	649	257
Social security contributions	437	303	134
Depreciation and amortisation of fixed assets	998	875	123
Provisions	251	18	233
Other expenses			0
Total operating expenses	5,891	4,379	1,512
OPERATING INCOME	-4,256	-2,779	-1,477
FINANCIAL INCOME/(EXPENSE)	396	-518	914
RECURRING INCOME BEFORE TAX	-3,860	-3,297	-563
EXCEPTIONAL INCOME/(EXPENSE)	-1	-5	4
Income taxes	501	471	30
NET INCOME	-3,360	-2,831	-529
Earnings per share in euros	-0.38	-0.39	

Cash flow statement

ITEMS	June-17	Dec-16
Net income	-3,360	-6,663
Depreciation, amortisation and provisions Capital gains on disposal, net of tax Other comprehensive income and expenses Cancellation of exceptional income on cancellation of debt	859	2,511
Cash flow from operations	-2,501	-4,152
Change in working capital requirements	-933	-252
(1) Net cash generated by (used in) operating activities	-3,426	-4,404
Acquisition of fixed assets Disposal of fixed assets, net of tax	-1,720	-6,065
(2) Net cash generated by (used in) investing activities	-1,720	-6,065
Capital increase Share premium Warrants Repayment of borrowings Commercial paper Debts on fixed assets Repayable advances Repayable advances	1,523 5,280 1 -188 -755 3,234 -260 2,820	640 3,508 1 -188 755 3,234 -188 3,234
(3) Net cash generated by (used in) financing activities	8,608	7,950
Change in cash and cash equivalents (1)+(2)+(3)	3,462	-2,519
Opening cash position	2,634	5,152
Closing cash position	6,096	2,634