



Press release

First-half 2021 results and business update

- Progress in the development of the drug portfolio
- Response to the BARDA Request For Proposals filed at the end of July
- Cash position under control

Dijon, 22 September 2021, 6:15 p.m.

CROSSJECT (ISIN: FR0011716265; Ticker: ALCJ), a specialty pharma company that is developing and will soon be marketing a portfolio of drug / device combinations for use in emergency situations, is announcing its 2021 half-year results and issuing a business update.

Patrick Alexandre, Crossject CEO, said: *“Crossject is resolutely pursuing its development programme and has signed a commercial agreement for ZENEO® Hydrocortisone with Eton Pharmaceuticals in a priority area for us, North America. In the United States, we have also submitted ZENEO® Midazolam to BARDA in response to its request for proposals issued in June. At the same time, we will soon be launching our first bioequivalence study. We are proud and enthusiastic about this progress.”*

Update on activity since the start of 2021

Signing of a licensing agreement with Eton Pharmaceuticals for ZENEO® Hydrocortisone

The first half of 2021 was marked by the signing of the licensing agreement with Eton Pharmaceuticals for ZENEO® Hydrocortisone in the United States and Canada.¹ After the distribution agreement for ZENEO® Midazolam signed with Desitin in July 2019, this new contract demonstrates the confidence of laboratories, not only in the innovative ZENEO® device but also in the technical maturity of our industrial facilities. The signing reflects the impact of the creation of Crossject’s American subsidiary in 2020, which facilitates

¹ See press release dated 15 June 2021



access to North American markets.

Crossject received \$0.5 million from this contract, and Eton Pharmaceuticals has escrowed an additional \$0.5 million to be paid at the next development milestone; further milestone payments totalling \$4 million are planned until marketing authorisations (MA) are granted.

As a reminder, ZENEO® Hydrocortisone addresses an unmet medical need in acute adrenal insufficiency, which can be fatal if not treated promptly. Eton Pharmaceuticals is responsible for all regulatory and commercial activities, including MA filings and related fees, distribution and promotion. Crossject is responsible for clinical development and manufacturing.

Response to the BARDA² request for proposals in July

Crossject filed its response to BARDA's request for proposals in the summer. The award date is not known at this time. Crossject will inform the market of the outcome of the process.

The request for proposals covers the further development of a Midazolam 10mg auto-injector, the development of a new paediatric dose, and the supply of up to 776,000 units to replace diazepam auto-injectors from the CHEMPACK National Strategic Stockpile.

Three priority developments for the submission of marketing authorisation applications: ZENEO® Midazolam, ZENEO® Hydrocortisone, and ZENEO® Epinephrine³

Within its development portfolio, Crossject is prioritising the development of ZENEO® Midazolam (epileptic seizure), ZENEO® Hydrocortisone (acute adrenal crisis) and ZENEO® Epinephrine (anaphylactic shock). With the support of a reliable ZENEO® needle-free injector and operational industrial facilities, the company can focus its work on the components of the marketing authorisation applications, in particular the production of the various batches required for the submission of regulatory dossiers and clinical bioequivalence studies.

For ZENEO® Midazolam, the last batch for the launch of the bioequivalence study has been manufactured. The study is due to be launched at the end of the year. Its purpose is to demonstrate bioequivalence between an intramuscular injection with a syringe and needle and that administered with ZENEO®.

² Biomedical Advanced Research and Development Authority.

³ Epinephrine is the name used in the USA for Adrenaline.



For ZENEO® Epinephrine, Crossject is continuing its development programme: the technical batches have been completed and stability tests are underway.

In addition to its priority drugs, Crossject is continuing to develop the rest of its drug portfolio (ZENEO® Naloxone, ZENEO® Terbutaline, ZENEO® Sumatriptan, ZENEO® Apomorphine, and ZENEO® Methotrexate), adopting a pragmatic approach to managing resources in line with commercial opportunities.

As a reminder, to obtain marketing authorisation for a ZENEO® drug, a dossier must be submitted to the health authorities, including different batches of ZENEO® **representative of commercial production**. This means that five to six ZENEO® batches must be produced for each drug, and therefore for each marketing authorisation application: technical batches, clinical batches, registration batches with their own production times. Crossject's industrial facilities are sized to produce the batches required for the submission of marketing authorisation applications and the start of commercial production.

Progress in other areas

In addition to these new steps, Crossject strengthened its partnership with Cenexi in the first half of the year to continue the gradual ramp-up of industrial production of ZENEO®.

Finally, the voluntary ISO 13485 certification process continues. To comply with the FDA's⁴ expectation of a 99.999% successful injection reliability for emergency use injectors and to demonstrate the high quality of its drug, Crossject launched the production of an additional batch of ZENEO® Midazolam early in the year. As the audit covered a complete production cycle of ZENEO®, the deadline has been extended.

Outlook

Since the beginning of 2021, Crossject has achieved a number of the objectives it set at the start of the year: continued production of ZENEO® units for the requirements of the marketing authorisation applications, response to the BARDA request for proposals, signature of a commercial agreement for the United States. Crossject's 2021 roadmap also included the completion of the clinical bioequivalence study for at least one product in its portfolio. The company will be in a position to launch it by the end of the year.

In the coming months, Crossject will continue to roll out its strategy on the strength of these latest advances, focusing on two areas:

- Continue to advance its work on the components of MA dossiers;
- Sign new commercial agreements, with a continued focus on North America.

⁴ Food and Drug Administration

Financial information as of 30 June 2021

€ thousand, as of 30 June	H1 2021	H1 2020
Operating income	3,176	2,086
Operating expenses	9,380	7,719
Purchases of raw materials and supplies	245	285
Other purchases and external expenses	2,955	2,120
Personnel expenses	3,116	2,816
Taxes and duties	105	105
Depreciation, amortisation and provisions	2,805	2,108
Other expenses	154	285
Operating profit/(loss)	(6,204)	(5,632)
Financial income/(expense)	(229)	(181)
Exceptional income/(expense)	21	(9)
Income tax	962	565
Net profit/(loss)	(5,450)	(5,258)

The financial statements six months to 30 June 2021 were approved by the Management Board on 20 September 2021 and presented at the Supervisory Board meeting of 21 September 2021.

Crossject's revenue increased by 52% to €3.2 million, driven by the signing of a licensing agreement with Eton Pharmaceuticals and the continued development of the drug portfolio, which had a positive impact on inventories and capitalised production.

Operating expenses were up 21% compared with the first half of the previous year. External expenses amounted to €3.0 million (+40%), mainly reflecting the development of the drug portfolio and related R&D expenses. Personnel expenses amounted to €3.1 million for the first half: the company continues to build up its workforce as it progresses.

Overall, the operating profit/(loss) was a loss of €6.2 million (€5.6 million in the first half of 2020).

After taking into account net financial income/(expense) and the Research Tax Credit, which was up sharply in line with the strength of R&D activity, net profit/(loss) was a loss of €5.4 million, **virtually stable** compared with the first half of 2020.

Crossject had a stronger cash position at the end of the first half of 2021. At the end of June 2021, the company had cash and cash equivalents of €9.2 million, compared with €8.3 million at the end of December



2020. The cash position benefited notably from the **improvement in cash flow** (-€2.6 million, vs -€3.3 million in the first half of 2020). In addition to the revenue generated by the agreement with Eton Pharmaceuticals, Crossject received proceeds from the conversion of bonds (€5.2 million), the 2020 Research Tax Credit, as well as grants and repayable advances, including the first tranche of the stimulus package (€0.71 million) and the balance of the €1 million PIAVE grant. Crossject thanks Bpifrance and France Relance for their support.

Cash flow should also be supplemented by resources stemming from the contribution of commercial contracts (existing and under discussion) to cover the needs of the coming year.

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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: Financial statements as of 30 June 2021

Income statement (in €k)	30/06/2021	30/06/2020	Change
Revenue	412	0	412
Stored production	132	37	95
Capitalised production	2,482	1,756	725
Operating subsidies	111	30	81
Reversals of depreciation, amortisation and provisions, transfer of expenses	39	263	(224)
Other income	0	0	0
Total operating income	3,176	2,086	1,090
Purchases of raw materials and other supplies	781	285	496
Change in inventory (raw materials and other supplies)	(536)	0	(536)
Other purchases and external expenses	2,955	2,120	835
Taxes, duties and similar payments	105	105	0
Personnel expenses	3,116	2,816	300
Depreciation, amortisation and provisions	2,387	2,041	346
Other provisions	418	67	351
Other expenses	154	285	(131)
Total operating expenses	9,380	7,719	1,662
Operating profit/(loss)	(6,204)	(5,632)	(572)
Financial income/(expense)	(229)	(181)	(48)
Exceptional income/(expense)	21	(9)	30
Income tax	962	565	398
Net profit/(loss)	(5,450)	(5,258)	(192)

STATEMENT OF CASH FLOWS (in €k)	30/06/2021	31/12/2020
Net profit/(loss)	(5,450)	(9,844)
Depreciation, amortisation and provisions	2,822	4897
Other income and expenses calculated	(14)	(33)
Cash flow from operations	(2,642)	(4,980)
Change in working capital requirements	13	(482)
(1) Net cash generated by (used in) operating activities	(2,629)	(5,462)
Acquisition of fixed assets	(2,903)	(6,096)
Disposal of fixed assets, net of tax		
(2) Net cash generated by (used in) investing activities	(2,903)	(6,096)
Redemption of convertible bonds		(80)
Bonds	5,240	5,240
Exercise of warrants		
Subscription of borrowings	130	6,000
Repayment of borrowings	(97)	(135)
Debts on fixed assets	(497)	695
Investment subsidies	716	
Repayable advances	967	210
(3) Net cash generated by (used in) financing activities	6,459	11,930
Change in cash and cash equivalents (1)+(2)+(3)	927	372
Opening cash position	8,277	7905
Closing cash position	9,204	8,277

BALANCE SHEET – ASSETS (in €k)	30/06/2021	31/12/2020	CHANGE
FIXED ASSETS			
Research and development expenses	7,973	7,528	445
Concessions, patents, trademarks and similar rights	8	0	8
Other intangible assets	20	9	11
Land	75	75	0
Property, plant and equipment	4,854	5,093	(239)
Fixed assets under construction	1,893	1,587	306
Financial assets	595	615	(20)
TOTAL ASSETS	15,418	14,907	511
CURRENT ASSETS			
Raw materials, other supplies	1,372	917	455
Work in process	417	608	(191)
State – receivables	2,097	8,352	(6,255)
Investment securities	154	144	10
Available cash	9,050	8,133	917
Prepaid expenses	529	528	1
TOTAL CURRENT ASSETS	13,619	18,683	(5,064)
TOTAL ASSETS	29,037	33,590	(4,553)

BALANCE SHEET – LIABILITIES (in €k)	30/06/2021	31/12/2020	CHANGE
SHAREHOLDERS' EQUITY			
Capital	2,587	2,390	198
Share premium	5,708	7,210	(1,502)
Regulated reserve	0	0	0
Retained earnings	(3,980)	(886)	(3,094)
<i>Profit/(loss) for the year</i>	<i>(5,450)</i>	<i>(9,844)</i>	<i>4,394</i>
Investment subsidies	701	0	701
TOTAL SHAREHOLDERS' EQUITY	(433)	(1,130)	(4)
Conditional advances	6,917	5,949	969
Provisions for contingencies and charges	832	806	26
BORROWINGS AND DEBT			
Bonds	5,052	10,498	(5,446)
Loans	7,905	7,956	(51)
Miscellaneous	2,693	2,609	84
Debts – Trade payables	2,212	2,355	(143)
Tax and social security liabilities	1,104	1,229	(125)
Debts on fixed assets	2,712	3,209	(497)
Deferred income	42	109	(67)
TOTAL DEBT	21,721	27,966	(6,245)
TOTAL EQUITY AND LIABILITIES	29,037	33,590	(4,553)