Press release

2021 annual results

First Marketing Authorization (MA) applications expected to be filed in 2023

Dijon, March 24, 2022

CROSSJECT (ISIN: FR0011716265; Ticker: ALCJ), a "specialty pharma" company developing and soon to market a portfolio of drug/device combinations for use in emergency situations, announces its 2021 results and provides a business update.

Patrick Alexandre, Chairman of the Management Board, said: "2021 *was an important year marked by many advances. The signing of the licensing agreement for ZENEO® Hydrocortisone in the United States and Canada is evidence of the interest for ZENEO® in strategic regions. The quality of our production facilities has also enabled us to release the batches required to prepare MA applications in compliance with our roadmaps and GMP regulations*[Erreur ! Signet non défini.]*. The first volunteers for the ZENEO® Midazolam bioequivalence study will receive injections in the second quarter of 2022. All our teams are focused on 2023, the estimated MA application filing date for two of our priority products, ZENEO® Midazolam and ZENEO® Hydrocortisone. Driven by the goal of saving lives in less than a minute after the onset of a crisis, our teams are making an unwavering commitment and I thank them for it."*

Business update

ZENEO® Midazolam and ZENEO® Hydrocortisone on track for MA application filing in 2023

The production of batches required to file Marketing Authorization (MA) applications has progressed satisfactorily for the three priority drugs in Crossject's portfolio. If these conditions continue, Crossject plans to file MA applications in the U.S. and Europe in 2023 for ZENEO® Midazolam and ZENEO® Hydrocortisone.

The compliance of the ZENEO® Midazolam clinical batch last December paved the way to launch all of the activities required upstream of the bioequivalence study: product coding, export to the CRO[1] (clinical service provider) conducting the study, recruitment of volunteers meeting the inclusion criteria and preparation of all the related documentation. The completion of these upstream activities takes some time due to strict regulatory standards. The first injections are expected during the second quarter of 2022. Crossject will notify the market.

More recently, in March, Crossject announced[2] the compliance of the industrial scale batch of ZENEO® Hydrocortisone. This step allows all the operations required to prepare the MA application file to be launched, including in particular the manufacturing of validation batches and the bioequivalence study. It marks a milestone in the contractual relationship with Eton Pharmaceuticals, with whom Crossject signed an exclusive distribution and promotion agreement for the United States and Canada in 2021[3]. This milestone triggered the payment of $0.5 million to Crossject, which has already been received.

At the same time, Crossject is continuing to develop the 3rd priority drug in its portfolio: ZENEO® Adrenaline, whose development plan has been discussed with the European (EMA) and American (FDA) regulatory authorities. Industrial scaling of ZENEO® Adrenaline is underway. Crossject intends to file the MA application for ZENEO® Adrenaline in 2024.

It should be noted that Crossject has decided to abandon development of the combination drug Apomorphine (Parkinson's disease), in favor of other projects with greater potential.

Other drugs in the portfolio continue to be developed, with Crossject prioritizing the development of drugs for which a distribution agreement has already been signed and taking market opportunities into account in its development schedule.

Industrial facilities prepared for the first commercial launches

2020 marked Crossject's transformation from an R&D company to an industrial company with solid production facilities. In 2021, Crossject continued its industrial approach always with an emphasis on quality.
Thanks to a very thorough verification program (more than 2,500 tests carried out under very rigorous conditions), which led to the implementation of strengthened checks, Crossject can justify an injection reliability rate of 99.999% for ZENEO®, the standard expected by the FDA[4] for auto-injectors used in emergency situations.

[1] Contract Research Organization
[2] See March 21, 2022 press release
[3] See June 15, 2021 press release
[4] Food and Drug Administration

As a reminder, the application to market a drug (MA) with the relevant authorities is not made on the basis of prototypes, but requires the production of several batches with qualified industrial equipment to demonstrate the repeatability of the product's quality and its stability over time (the target shelf life is two to three years), before a clinical demonstration is made. Crossject's installed production capacity is about 0.5 million ZENEO® units per year and can be increased to more than 6 million units per year by simply duplicating the current equipment as customer orders come in.

In May 2021, with a view to ramping up industrial production of ZENEO®, Crossject has strengthened its partnership with Cenexi, which handles the filling and final assembly of the ZENEO® auto-injector at its site in Belgium.

At the end of 2021, Crossject obtained the Good Manufacturing Practices certificate issued after inspection by the ANSM (French competent authority). This certificate confirms that the Company meets the quality level set by the drug manufacturing regulations. As a reminder, Crossject obtained pharmaceutical establishment status in 2019, which allows it to release clinical batches and perform checks on finished products for human use.

The ISO 13485 certification program is underway. A four-week audit was carried out in early 2022 at both Crossject sites (Dijon and Gray). The process is progressing in line with the Company's expectations.

Crossject is waiting for the results of the BARDA request for proposals

BARDA's review of the responses to its request for proposals for the development and supply of midazolam 10mg auto-injectors and a pediatric dose is underway. The authority did not provide a projected timeline for feedback to respondents. As a reminder, Crossject has undertaken to communicate BARDA's response to the market as soon as possible after the process is completed.

The response and exchanges for a request for proposals from such an authority are very demanding. Crossject's teams have responded with rigor and determination and have acquired skills that could be very useful for future requests for proposals.

Business development: interest shown in ZENEO®

The increased interest in ZENEO® resulted in the signature of a licensing agreement in the United States and Canada with Eton Pharmaceuticals for ZENEO® Hydrocortisone in June 2021.

Crossject is currently pursuing discussions on molecules and/or regions not yet covered by commercial agreements.

One of the major advantages of ZENEO® is its ease of use in complete safety; this design has been

developed and validated with nearly 1,000 people. ZENEO® makes it possible to act in less than one minute - from taking it out of the box to injecting it - which is crucial in emergency situations.
In addition to molecules for emergency treatment, ZENEO® is also very attractive for high-priced biotechnology molecules.

Crossject, a company resolutely committed

Crossject's Gaïa rating has risen from 15 to 46 in two years reflecting the actions taken since 2018 in this area.

The gender equality index 2021 reached 99/100 in 2021, a 16-point increase compared to the previous year. Crossject's gender equality policy has been strengthened by signing an agreement on professional equality in 2021.

Outlook

After a 2021 and early 2022 marked by reaching several key milestones, Crossject intends to continue executing its roadmap in 2022, focusing in particular on the following projects:

- Production of ZENEO® units for the purposes of MA applications,
- Completion of the clinical bioequivalence study for ZENEO® Midazolam,
- Signing new commercial agreements.

Crossject believes it is not impacted by the war in Ukraine to date. The Company has no suppliers in Ukraine nor Russia on which it depends for the supply of its raw materials and components. However, Crossject is watching how the situation evolves and its potential repercussions.

The strong increase in commercial discussions in 2021 enables Crossject to confirm its market potential estimates. Crossject estimates that the long-term revenues of its distributor customers should be around €900 million for the products currently in the portfolio, with nearly half of this from the three priority products.

All of Crossject's teams are focused on the objective of submitting the first MA applications in 2023.

Financial information as at December 31, 2021

€ thousands, as at December 31	2021	2020
Operating income	**6,772**	**5,731**
Operating expenses	**(18,594)**	**(16,403)**
Costs of Raw materials and supplies	(954)	(986)

Other purchases and external expenses	(5,901)	(4,885)
Personnel expenses	(6,183)	(5,328)
Taxes and duties	(202)	(201)
Amortization, depreciation and provisions	(5,013)	(4,556)
Other expenses	(342)	(447)
Operating profit (loss)	**(11,823)**	**(10,672)**
Financial income (expense)	**(774)**	**(250)**
Exceptional income (expense)	**81**	**(567)**
Income tax	1,818	1,646
Net profit (loss)	**(10,698)**	**(9,844)**

Financial statements as at December 31, 2021, approved by the Management Board on March 23, 2022 and presented to the Supervisory Board on March 24, 2022. Audited financial statements.

As at December 31, 2021, operating income stood at €6.8 million, up 18%. It includes €0.9 million of revenues resulting from the signature of the licensing agreement with Eton Pharmaceuticals for ZENEO® Hydrocortisone and reaching the release of the ZENEO® Midazolam clinical batch milestone. In addition, capitalized production increased by 16% to €5.4 million due to continued research and development.

During the year, while making significant development progress, Crossject maintained control over its cost structure. Operating expenses thus rose a moderate 13% compared to operating income. Other purchases and external expenses amounted to €5.9 million, compared with €4.9 million at the end of 2020, due in particular to the progress of production of the various batches of several drugs in the portfolio and the costs incurred in responding to the BARDA request for proposals. At the end of 2021, Crossject had 94 employees, stable compared to end-2020. Personnel expenses at the end of 2021 rose to €6.2 million, compared with €5.3 million last year taking into account the base effect of the hiring carried out in 2020.

Overall, operating profit (loss) stood at -€11.8 million at the end of December 2021.

Financial income (expenses) in 2021 include financing costs related to the rescheduling of part of the financial debt and amounted to -€0.7 million.

After taking into account the exceptional income (expense) and an increased R&D Tax Credit (€1.8 million versus €1.6 million in 2020), net loss stood at €10.7 million.

As at December 31, 2021, Crossject has cash and cash equivalents of €10 million (€8.3 million at end-2020). To finance its development, the Company has issued bonds (€5.2 million raised in April 2021 and €7.5 million in December 2021) and received public funding, grants and subsidies (€1 million paid by Bpifrance under the PIAVE program, €1.5 million under the stimulus plan).

Considering the rich "news flow" expected in the first half of 2022, Crossject will adapt its future sources of funding like commercial revenues, contributions from strategic partners, grants and subsidies, or financial transactions.

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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 Euronext Growth Paris since 2014, and benefits from Bpifrance financing.

Appendix: Financial statements as at December 31, 2021

Income statement (in € thousands)	12/31/2021	12/31/2020	Change
Revenue	912	0	912
Stored production	170	683	(513)
Capitalized production	5,383	4,624	759
Grants and subsidies	185	220	(35)
Reversals of depreciation, amortization and expense transfers	98	184	(86)
Other income	24	20	4
Operating income	6,772	5,731	1,041
Purchases of raw materials and other supplies	1,143	904	239
Change in inventory (raw materials and other supplies)	(189)	81	(270)
Other purchases and external expenses	5,901	4,885	1,016
Taxes and duties	202	201	1
Personnel expenses	6,183	5,328	855
Amortization and depreciation	4,490	3,949	541
Other allowances	523	607	(84)
Other expenses	342	447	(105)
Operating expenses	18,595	16,403	2,192
Operating profit (loss)	**(11,823)**	**(10,672)**	**(1,151)**
Financial income (expense)	**(774)**	**(250)**	**(524)**
Exceptional income (expense)	**81**	**(567)**	**648**
Employee shareholding		1	(1)
Research Tax Credit	1,818	(1,646)	3,464
NET PROFIT (LOSS)	**(10,698)**	**(9,843)**	**(855)**

BALANCE SHEET - ASSETS IN € THOUSANDS	12/31/2021	12/31/2020	CHANGE
FIXED ASSETS			
R&D	9,123	7,528	1,595
Patents and trademarks	6	0	6
Other intangible assets	11	9	2
Land	89	75	14
Property, plant and equipment	4,631	5,093	(462)
Fixed assets in progress	2,426	1,587	839
Long-term investments	516	615	(99)
TOTAL FIXED ASSETS	**16,802**	**14,907**	**1,895**
CURRENT ASSETS			
Raw materials, other supplies	863	917	(54)
Production in progress	503	608	(105)
Advances and prepayments	294	267	27
Trade receivables	44		44
State and other receivables	1,931	8,086	(6,155)
Investment securities	154	144	10
Cash and cash equivalents	9,830	8,133	(1,697)
Prepaid/deferred expenses	923	528	395
TOTAL CURRENT ASSETS	**14,543**	**18,683**	**(4,140)**
TOTAL ASSETS	**31,344**	**33,590**	**(2,246)**

BALANCE SHEET - LIABILITIES IN € THOUSANDS	12/31/2021	12/31/2020	CHANGE
SHAREHOLDERS' EQUITY			
Share capital	2,604	2,388	216
Issuance premiums	6,036	7,212	(1,176)
Statutory reserves	0	0	0
Retained earnings	(3,980)	(886)	(3,094)
Profit (loss) for the year	(10,698)	(9,844)	(854)
Investment grants	665	0	665
TOTAL SHAREHOLDERS' EQUITY	**(5,372)**	**(1,130)**	**(4,242)**
Conditional advances	7,188	5,949	1,239
Provisions for contingencies and charges	810	806	4
BORROWINGS AND DEBT			
Bonds	12,587	10,498	2,089
Borrowings	7,946	7,956	(10)
Miscellaneous debts	2,794	2,611	183
Trade payables	1,961	2,355	(394)
Tax and social security liabilities	1,183	1,227	(44)
Liabilities on fixed assets	2,247	3,209	(962)
Deferred income	0	109	(109)
TOTAL DEBT	**28,718**	**27,966**	**752**
TOTAL LIABILITIES	**31,344**	**33,590**	**(2,246)**

CASH FLOW STATEMENT in € thousands	12/31/2021	12/31/2020
Net profit (loss)	**(10,698)**	**(9,844)**
Amortization, depreciation and provisions	5,078	4,897
Other calculated income and expenses	(28)	(33)
Self-financing capacity	(5,648)	(4,980)
Change in working capital requirement	(458)	(482)
(1) Net cash flow generated from (used in) operating activities	**(6,106)**	**(5,462)**
Acquisition of fixed assets	(6,422)	(6,096)
Disposal of fixed assets, net of taxes		
(2) Net cash flow generated from (used in) investing activities	**(6,422)**	**(6,096)**
Repayment of convertible bonds		(80)
Bond	13,066	5,240
Grant	716	
New loans	369	6,000
Loan repayments	(195)	(135)
Liabilities on fixed assets	(962)	695
Repayable advances	1,239	210
(3) Net cash flow generated from (used in) financing activities	**14,233**	**11,930**

Change in cash and cash equivalents (1)+(2)+(3)	**1,705**	**373**
Opening cash balance	**8,277**	**7,905**
Closing cash balance	**9,983**	**7,269**