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# CROSSJECT unveils its strategic choices and new roadmap

- Priority given to emergency treatment drugs
- Priority focus on penetrating the US market
- Capitalisation on a first-class industry partnership with CENEXI and internalisation of certain manufacturing operations
- Revision of regulatory timetable: Approval to Market applications filed for 6 products in 2018

**CROSSJECT, a specialty pharma developing a portfolio of combined advanced therapy medicinal products for emergency use, has strategically revised its operations and roadmap.**

## Restructuring and streamlining: enhancement of the partnership with CENEXI and internalisation of certain strategic manufacturing operations

### Enhancement of the partnership with CENEXI

Considering how exceptionally well the partnership with CENEXI has gone, CROSSJECT has decided to strengthen and ramp up this arrangement to focus all of its strengths on the US market, could ultimately be expected to represent nearly 75% of the company's business.

CROSSJECT will have at its disposal a filling line meeting the highest international standards (particularly the US Food and Drug Administration), with a production capacity of 10 million units/year, i.e. 4-5 times the initially projected volumes.

An additional fast-track assembly line to produce clinical batches should be operational as of H1 2017, and will secure the regulatory process.

In its commitment to implementing the plan, CENEXI has provided a 25-person team (over 15 FTEs), working non-stop with CROSSJECT.

Pascal Oromi, Managing Director of CENEXI Services, said: *"This partnership is a great opportunity to highlight the value of our regulatory expertise, particularly through our experience with the FDA, and our manufacturing expertise, all to benefit a company with a promising future. CROSSJECT boasts a unique technology as well as an extensive product portfolio. From our perspective, this partnership offers high volume potential. And, thanks to our efficient assembly line, we can keep cost of goods under control. We firmly believe that this partnership will be a success for CENEXI and CROSSJECT alike."*

The CROSSJECT/CENEXI partnership calls for a minimum 5-year exclusivity agreement, in exchange for CENEXI's investment in manufacturing facilities, and covers the entire range of products and geographic areas.

## Internalisation of certain highly specific operations

In addition to this agreement, CROSSJECT has streamlined its organisational structure by internalising a number of operations that are highly specific to ZENEO®.

The inauguration of the new CROSSJECT facilities in Dijon this week, attended by François Rebsamen, Mayor of Dijon, is a key milestone in the company's three-prong restructuring process:

- The combination of its non-pharmaceutical activities at the CROSSJECT Gray site (Haute-Saône), where the tubes are dipped and the actuator assembled, already operational.

- The preparation of primary packaging materials at the new Dijon site (PIAVE financing), whose implementation will feed CENEXI's fast-track line from Q1 2017.

- Filling and final assembly operations handled by CENEXI.

## New priorities for the drug portfolio

To make the most of this partnership and optimise its ROI, CROSSJECT has redefined the priorities of its 7-product pipeline based on 4 criteria:

- priority given to life-saving products (also higher added value and possible access to the FDA's fast-track procedure),

- priority given to products in the advanced development phase and thus soon ready for licensing agreements in the US, with upfront payments upon signing,

- priority given to products calling for fewer resources to submit Approval to Market applications,

- priority given to products that can be registered with the same Approval to Market application in Europe and the US.

Ultimately, these priorities mean Crossject is stepping up its efforts on ZENEO® Sumatriptan, ZENEO® Midazolam, ZENEO® Adrenaline and ZENEO® Hydrocortisone, according to the following timetable:

| Product | *Initial date of submission of Approval to Market application (Europe)* | New submission date (Europe) | New submission date (US) |
|---|---|---|---|
| SUMATRIPTAN *Acute migraine Facial algia* | *H1 2017* | H1 2018 | H2 2018 |
| MIDAZOLAM *Epilepsy* | *H2 2017* | H2 2018 | H1 2019 |
| ADRENALINE *Anaphylactic shock* | *H2 2017* | H2 2018 | H1 2019 |
| METHOTREXATE *Rheumatoid arthritis* | *H2 2016* | H2 2018 | H1 2020 |
| HYDROCORTISONE *Acute adrenal insufficiency* | *H1 2017* | H2 2018 | H1 2019 |
| NALOXONE *Overdose* | *H1 2018* | H2 2018 | H1 2019 |
| APOMORPHINE Parkinson's Disease | *H2 2018* | H1 2019 | H1 2020 |

** Approval to Market is generally obtained 1 year after the application is filed.*

The aim of increasing and securing US market penetration with emergency-use drugs will set back the initial timetable by an average of 12 months. The other products will benefit from the learning curve on the manufacturing process.

## Financing overview at 30/09/2016

At 30 September 2016, cash and cash equivalents amounted to €2m. The company can also count on additional cash of €11m over the next 18 months:

- €5.5m from the exercise of 850,000 warrants linked to the Equity line agreement, based on an exercise price assumption of €6.5,
- €4.3m in repayable grants provided for under the PIAVE contract (o/w €2.8m in early 2017)
- €0.2m in subsidies,
- €1.0m in research tax credits and other tax incentives

Total potential FCF amounts to €13m, excluding new commercial agreements and not counting the 178,078 treasury shares held.

In addition, the company will receive upfront payments before end-2017 when it signs distribution licensing agreements with pharmaceutical companies, particularly in the US for ZENEO® Sumatriptan and ZENEO® Midazolam.

## Crossject's priorities for 2017

Drawing on its enhanced cooperation with CENEXI, CROSSJECT's priority for H1 2017 will be getting the fast-track line up and running for the initial batches needed to submit the Approval to Market applications for ZENEO® Sumatriptan and ZENEO® Midazolam.

At the same time, capitalising on CENEXI's regulatory experience with the FDA and the restructuring of the drug portfolio, CROSSJECT will be in a stronger position to sign a distribution licensing agreement in the US for ZENEO® Sumatriptan by the end of 2017 and subsequently for ZENEO® Midazolam.

Over the period, CROSSJECT, with the help of CENEXI, will also provide all the necessary support to its client in charge of developing ZENEO® Adrenaline.

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## About CROSSJECT • www.crossject.com

CROSSJECT (ISIN code: FR0011716265 Ticker: ALCJ) is a specialty pharma that develops and plans to market a portfolio of drugs primarily designed for emergency use (opiate overdoses, acute migraines, epilepsy, temporary paralysis in Parkinson's patients, anaphylactic shock, acute adrenal insufficiency, rheumatoid arthritis). With its patented needle-free injection system, Zeneo®, Crossject has created an effective solution for the fast and easy self-administration of drugs in emergency situations. Crossject has secured positions in fast-growing markets worth over $10 billion*. Crossject has been listed on the Paris Alternext market since February 2014.
*Sources*: Datamonitor 2015, Anaes 2015, Int J Emerg Med (2008), Company.*

## About CENEXI • www. cenexi.com

With nearly 20 years' experience, over 1,000 employees and revenue of €130 million, CENEXI is a major player in the global pharmaceutical industry. CENEXI is exclusively focused on pharmaceutical development and manufacturing. Its mission is to provide its clients with a turnkey solution in a variety of fields: developing new formulations, managing the transfer of product portfolios, and filling orders to meet its clients' needs.

## Disclaimer