Crossject announces S1 2014 business update

Crossject continues the development of its supergeneric product's portfolio

Chenôve, 22nd September 2014 – CROSSJECT (ISIN : FR0011716265 ; Mnémo :ALCJ), the creator of ZENEO®, the world's most advanced needle-free injection system, announces its business update for the first half of 2014 ending on 30th June.

- Progress in the industrialisation of Zeneo®, with the finalisation of the central production chain elements and the recruitment of a supply chain director
- Launch, in July 2014, of the single bioequivalence clinical study needed to support the marketing authorisation application for Zeneo® Methotrexate in Europe
- Zeneo® Adrenaline well positioned to benefit from the possible new regulations covering marketed epi-pens
- Advanced discussions towards the launch of a new product designed for use in emergency situations
- Cash position : €14m as of 30th June 2014

Patrick Alexandre, CEO and founder of Crossject announces: *"Since the beginning of the year, Crossject has intensified the development activities needed to introduce our first supergeneric products starting in 2015. The success of our initial public offering allowed us to complete the first phases of setting up the industrial supply chain for Zeneo®. We are also making progress in expanding our pipeline and are in advanced discussions concerning the development of a new supergeneric product aimed at emergency situations of illnesses."*

During the first half of 2014, Crossject has reinforced its financial structure in order to be able to continue the development of its portfolio of self-injection needle-free products based on ZENEO®. This unique system allows intradermal, subcutaneous and intramuscular delivery.

Crossject also completed the preparatory work needed for the planned bioequivalent study for Zeneo® Methotrexate. The design of the Zeneo® Methotrexate device has been adapted in partnership with the French association of arthritis and chronic inflammatory rheumatisms.

The bioequivalence study was launched in July 2014 and is the only clinical study needed to support the filing of the marketing authorisation in Europe. To date, this study is progressing as planned and the results are expected by the end of 2014. This means that Crossject is on track to file a marketing authorization request submission in France for Zeneo® Methotrexate by the end of 2015. Crossject already has a partner in place to commercialize Zeneo® Methotrexate in France.

Zeneo® Adrenaline is well placed to establish itself as an indispensable product to treat people suffering an emergency allergic reaction. At present the European Medicine Agency (EMA) is analysing carefully the effectiveness of the epi-pens with needles which are currently on the market. They are particularly concerned about whether non-medical personnel can use these pens to deliver adrenaline intramuscularly. This is necessary if the drug is to work successfully.

Zeneo® Adrenaline, which has proved in a number of clinical studies that it can deliver adrenaline intramuscularly, even when used by non-medical personnel, is therefore in an extremely good position to take advantage of any new regulations which may be introduced in Europe. Crossject is waiting for the conclusions from the EMA review, which should be released by the end of 2014 before defining the protocol the Zeneo® Adrenaline bioequivalence study. This will allow it to take into account any new evaluation criteria and would put it in a good position, subject to regulatory approval, to rapidly commercialise this novel product.

Crossject has completed the first key stage of the Zeneo® industrialisation process by finalising the implementation of the central elements of the production chain. The thermal treatment of glass tubes and the moulds which allow the creation of the key components for ZENEO® are now both operational. Furthermore Crossject has finalised the recruitment of a director of the supply chain, who joined the team in June 2014.

Besides, Crossject is in advanced negotiations for the launch of a new supergeneric product with a partner, aimed for use in emergency situations.

In June 2014, Patrice Coissac joined Crossject's Supervisory Board. His knowledge of international medical issues, his operational expertise and his previous experience in various large international pharmaceutical groups will enable to make an important contribution to the successful implementation of Crossject's marketing plan to commercializeZeneo starting in 2015.

A solid financial situation

At the end of 2013, the company announced its intention to raise additional funds by way of an Initial Public Offering on Alternext of Euronext Paris. The successful IPO closed in February 2014, enabling the company to raise €17 million. These funds are designed to give the company the financial resources needed to put in place its industrial production capability and to carry out the activities to obtain marketing authorizations for its current portfolio of products.

On June 30th 2014, Crossject had cash and cash equivalents of € 14m compared with €2.4m on the 31st December 2013 and €3.2m on the 30th June 2013.

Operating income was € 0.8m compared with €0.5m for the first six months of 2013. In the first half of 2014, total operating expenses of the company rose to €3.16m Euros compared with € 1.54m for the same period in 2013.

During the first six months of 2014, the operating loss totalled €2.4m compared with €1.1m for the first term of 2013. The net loss was €2.1 m compared with €0.55m for the same period from the previous fiscal period.
This variation is due to the acceleration of Crossject's development activities particularly since the beginning of 2014.. This is due to the implementation of the first elements of the industrial production chain, the start of work for the market authorization fillings (in Europe and the US) for the 3 first supergenerics (including bioequivalence studies) and the increase in total employee costs as we expanded the project management and industrialisation teams.

During the first half of 2014, Crossject has made a number of changes to its shareholder structure.

Crossject implemented the planned repayment of a bond, which was provided by ETV Capital, of which €1.45m, and the completion date being due in 2015. As a result of this planned bond repayment, there is a financial charge of € 0.4m (capital and interest).

Crossject and Crossject Investment Partners (CIP), a shareholder of Crossject, have merged r, in accordance with the plans provided in a reference document that was approved by the AMF on the 11th December 2013 under the number I.13-051. This operation, approved by the CROSSJECT and CIP extraordinary general meetings, has allowed CIP shareholders, mostly legal persons who have supported Crossject since 2012, to become direct shareholders in the company. As a result, Crossject holds 178,078 of its own shares, that are valued at €1.840m..

The complete "bi-annual financial report "will be available on the 30th September 2014 after the close of trading on the company website www.crossject.com.

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About Crossject • www.crossject.com

Crossject is using its world-leading needle-free injection system, ZENEO™ to develop an attractive pipeline of high value SUPERGENERICS or New Therapeutics Entities. These needle-free products, which are based on well-known injectable drugs (chemicals & biologics), are designed to enhance patient safety, compliance and comfort.
Crossject's needle-free, pre-filled, single-use ZENEO ™ injection systems are unique in that they can be tailored to deliver drugs intra-dermally, subcutaneously and intramuscularly. This means that ZENEO™ can allow a wide range of drugs and vaccines for a broad range on indications to be developed and approved in a very short period of time. Outside its own portfolio of SUPERGENERICS, Crossject anticipates partnering ZENEO with other pharma/biotech looking to improve the life cycle management of their key drugs or biologics.

CROSSJECT is listed on Alternext Paris (Mnemo : ALCJ, ISIN : FR0011716265)

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