EDISON

Crossject

A reinforced cash position

Financial and development update

Pharma & biotech

Crossject recently announced that it has received regulatory approval to launch the bioequivalence study for Zeneo Midazolam (being developed for the acute treatment of epileptic seizures) in healthy volunteers. This puts the company on track for the expected H218 EU filing and the H119 US filing. Due to this milestone, Crossject has received €2.9m from Bpifrance as part of the Programme des Investissements d'Avenir (PIAVE). Also, the company has successfully completed a €5m rights offering.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/15	2.4	(6.7)	(0.85)	0.0	N/A	N/A
12/16	1.4	(7.3)	(0.85)	0.0	N/A	N/A
12/17e	2.9	(5.4)	(0.44)	0.0	N/A	N/A
12/18e	0.0	(9.6)	(0.85)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Zeneo Midazolam targets under-served market

Currently, there is only one at-home treatment approved in the US for the acute treatment of epileptic seizures, a rectal gel version of diazepam, which is part of the benzodiazepine class along with midazolam. Otherwise, patients need to be taken to the hospital if their seizures do not end by themselves.

Pipeline expected to progress in 2017

By the end of 2017, the company expects to complete bioequivalence studies for Zeneo Midazolam, Sumatriptan and Epinephrine/Adrenaline (by its partner) with Naloxone and Hydrocortisone studies to follow soon thereafter. Crossject has already successfully completed bioequivalence studies for Zeneo Methotrexate.

An additional focus on partnerships

Crossject recently announced that it is working with a London-based advisory company with a presence in North America and a history of successful business development deals to license Zeneo Sumatriptan for the treatment of acute migraines in the US and Canada. Additionally, the company has enlisted Bionest Partners, a healthcare-focused consulting firm, to prepare a commercial assessment for Zeneo Midazolam for use in business development activities.

Valuation

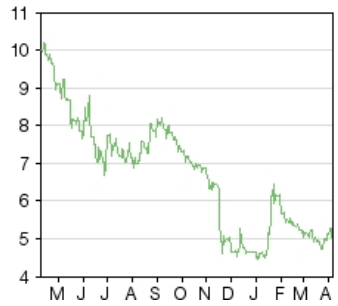
We have adjusted our valuation to €87.4m or €9.91 per share, from €68.2m or €9.91 per share. Our total valuation increased mainly due to rolling forward our NPVs to 2017, extending our expected patent protection to 2036 following the announcement of new patents, a higher net cash balance following the successful €5m rights offering and the €2.9m milestone payment related to Midazolam that was received from PIAVE. This was mitigated by a higher share count as the rights offering was dilutive. Between now and projected profitability in 2020, we forecast a total funding need of €20m (previously €35m).

7 April 2017

Price	**€5.02**
Market cap	**€44m**

Net debt (€m) at 31 December 2016	1.4
Shares in issue	8.8m
Free float	60.26%
Code	ALCJ
Primary exchange	Euronext
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	0.1	10.8	(50.0)
Rel (local)	(3.0)	5.6	(58.2)
52-week high/low		€10.0	€4.4

Business description

Crossject has several programmes in development based on its proprietary needle-free injection system, ZENEO. The first to market will be Zeneo Sumatriptan, which the company expects to be commercialised in 2019. Over the course of 2019 and 2020, the company expects to launch proprietary versions of six other products on its ZENEO platform.

Next events

Completion of Sumatriptan bioequivalence study	H217
Completion of Midazolam bioequivalence study	H217
Midazolam or Sumatriptan US partnership	2017

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Investment summary

Crossject's proprietary needle-free injection platform, ZENEO, can be used for up to 200 drugs (both small molecule and biologic) that it has identified, although currently the company is focusing mainly on acute treatments where the speed of treatment is an important factor for patients.

Exhibit 1: Crossject pipeline

Product	Indication	Expectation for submission (EU)	Expectation for submission (US)	Notes
Sumatriptan	Acute migraine	H118	H218	Bioequivalence study expected to be completed in 2017
Midazolam	Acute epilepsy seizures	H218	H119	Bioequivalence study given regulatory go-ahead and expected to be completed in 2017
Epinephrine/Adrenaline	Anaphylactic shock	H218	H119	Bioequivalence study expected to be completed in 2017
Methotrexate	Rheumatoid arthritis	H218	H120	Bioequivalence study completed
Hydrocortisone	Acute adrenal insufficiency	H218	H119	Bioequivalence study expected to be completed in 2017
Naloxone	Opioid overdose	H218	H119	Expect to confirm formulation and pre-stability studies and receive regulatory authorization for bioequivalence studies
Apomorphine	Parkinson's disease	H119	H120	Expect to confirm formulation and pre-stability studies

Source: Crossject

Zeneo Midazolam for the acute treatment of epileptic seizures

Crossject recently announced that it has received regulatory approval to launch the bioequivalence study for Zeneo Midazolam (being developed for the acute treatment of epileptic seizures) in healthy volunteers. This puts it on track for the expected H218 EU filing and the H119 US filing.

According to the Centers for Disease Control (CDC), 2.9 million people have active epilepsy in the United States. The prevalence of epilepsy in Europe is 3.4 million with 20-30% having more than one seizure per month.[1] The average seizure lasts less than two minutes[2] but the longer a seizure does last the harder it is to stop with treatment and the greater the likelihood of complications. For seizures lasting 10-29 minutes, only 43% cease without treatment and once they reach 30 minutes in length (officially known as status epilepticus), only 7% cease without treatment, with 19% of affected patients dying.[3]

Optimally, the patient would be treated at home as the trip to the hospital can waste very valuable time. However, only one at-home treatment is approved in the US, a rectal gel version of diazepam, which is part of the benzodiazepine class along with midazolam. While rectal diazepam does work quickly, it is not patient friendly as it involves injecting a liquid inside the rectum of a patient while they are having a seizure, which may be convulsive. Nevertheless, rectal diazepam achieved over $100m in sales before going generic in 2010.

In Europe, a buccal form of midazolam, known as Buccolam, is marketed by Shire. It is a liquid that needs to be inserted slowly into the space between the gum and cheek, possibly not the most convenient way to administer a drug to someone with a convulsive seizure. According to EvaluatePharma, sales in 2015 were $18m, though Shire does not disclose sales specifically for that product, given its small size.

Crossject's Zeneo Midazolam should have a similar profile to intramuscular and buccal midazolam, with a 5-10 minute onset but short duration of action, ideal for home use. It may even have an advantage over intramuscular auto-injectors in penetrating the muscle in high BMI patients, which it recently demonstrated in a positive 97-patient MRI study.

1 Forsgren L. et al., European Journal of Neurology 2005 Apr;12(4)245-53

2 Alford E et al., Journal of Pediatric Pharmacology and Therapeutics 2015;20(4):260-289

3 DeLorenzo R. et al., Epilepsia 1999 Feb;40(2):164-9

We currently assume approval in the US and EU in 2020 for the product, with pricing of €100 and €25 per dose, respectively (approximately the average price of Buccolam in Europe). Peak sales are estimated at €50.8m in the US (8% peak penetration) and €6.8m in the EU (12% peak penetration). Our penetration estimates are conservative due to the competitive and genericised nature of the market. We believe Crossject will require a marketing partner in the different regions. In terms of milestones, we model €2m upfront/approval milestones for EMA and FDA approval and a further €4m in commercial milestones. We estimate royalties of 20% for both the US and EU.

Valuation

We have adjusted our valuation to €87.4m or €9.91 per share, from €68.2m or €9.91 per share. Our total valuation increased mainly due to rolling forward our NPVs to 2017, extending our expected patent protection to 2036 following the announcement of four new patents, a higher net cash balance following the successful €5m rights offering and the €2.9m milestone payment related to Midazolam that was received from PIAVE. This was mitigated by a higher share count as the rights offering was dilutive. We expect to review our valuation upon completion of bioequivalence studies as well as the announcement of partnerships, especially in the US market.

Exhibit 2: Crossject valuation table

Product	Main indication	Probability of success	Launch year	WW peak sales (€m)	Patent protection	Royalty	rNPV (€m)
Methotrexate	Rheumatoid arthritis	30%	2020	€100	2036	20%	€8.8
Sumatriptan	Acute migraine	60%	2019	€82	2036	20%	€13.8
Adrenaline	Anaphylactic shock	60%	2020	€133	2036	25% US, 20% EU	€34.8
Midazolam	Acute epileptic seizures	60%	2020	€58	2036	20%	€9.7
Hydrocortisone	Acute adrenal crisis	60%	2020	€9	2036	20%	€0.7
Naloxone	Opioid overdose	60%	2020	€14	2036	20%	€1.1
Apomorphine	Parkinson's disease	30%	2020	€53	2036	20%	€11.9
Total							**€80.8**
Cash and cash equivalents (Q416 + rights offering + PIAVE payment) (€m)							€6.52
Total firm value (€m)							**€87.36**
Total basic shares (m)							8.81
Value per basic share (€)							**€9.91**
Stock options (12/2016e, m)							0.62
Weighted average exercise price (€)							€2.68
Cash on exercise (€m)							€1.67
Total firm value (€m)							€89.03
Total number of shares (m)							9.4
Diluted value per share (€)							€9.44

Source: Edison Investment Research, Crossject reports

Financials

As of Q416, the company had €2.6m in cash. Subsequent to the end of the quarter, the company received a €2.9m milestone payment for the advancement of Midazolam and has also announced the completion of a €5m rights offering. We have lowered our expectations for SG&A expenses in 2017 and 2018 by €1.9m and €2.0m per year, respectively, due to continued control on that expense line. Between now and projected profitability in 2020, we forecast a total funding need of €20m (previously €35m). Note that we are not assuming recurring grants and subsides (such as around €3m in additional milestone payments from Bpifrance), other than R&D credits, at this stage for FY18 and beyond.

Exhibit 3: Financial summary

	2014	2015	2016e	2017e	2018e
Year end 31 December	French GAAP	French GAAP	French GAAP	French GAAP	French GAAP
PROFIT & LOSS					
Revenue	1,744	2,370	1,427	2,900	0
Cost of Sales	0	(0)	0	0	0
Gross Profit	1,744	2,369	1,427	2,900	0
R&D Expenses	(2,421)	(3,077)	(4,384)	(4,800)	(5,520)
SG&A and Other Expenses	(3,388)	(4,808)	(2,630)	(2,841)	(3,068)
EBITDA	(4,066)	(5,516)	(5,587)	(4,741)	(8,588)
Operating Profit (before GW and except.)	(5,108)	(7,013)	(7,291)	(4,741)	(8,588)
Intangible Amortisation	0	0	0	0	0
Other	(0)	0	0	0	0
Exceptionals	0	0	0	0	0
Operating Profit	(5,108)	(7,013)	(7,291)	(4,741)	(8,588)
Net Interest	(36)	(19)	(38)	(659)	(1,058)
Other	(160)	299	(429)	0	0
Profit Before Tax (norm)	(5,334)	(6,720)	(7,329)	(5,399)	(9,646)
Profit Before Tax (FRS 3)	(5,304)	(6,732)	(7,758)	(5,399)	(9,646)
Tax	968	1,045	1,095	1,440	1,656
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	(4,366)	(5,675)	(6,234)	(3,959)	(7,990)
Profit After Tax (FRS 3)	(4,336)	(5,687)	(6,663)	(3,959)	(7,990)
Average Number of Shares Outstanding (m)	6.7	6.7	7.3	9.0	9.4
EPS - normalised (c)	(65.64)	(85.33)	(85.19)	(43.99)	(85.36)
EPS - FRS 3 (€)	(0.65)	(0.86)	(0.91)	(0.44)	(0.85)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	5,521	5,936	9,252	9,704	10,048
Intangible Assets	2,327	2,330	2,506	2,506	2,506
Tangible Assets	888	1,727	5,636	6,089	6,432
Other	2,305	1,878	1,109	1,109	1,109
Current Assets	12,853	7,943	4,997	9,811	6,477
Stocks	0	761	398	398	398
Debtors	1,926	1,991	1,966	1,966	1,966
Cash	10,927	5,139	2,634	7,447	4,114
Other	0	52	0	0	0
Current Liabilities	(2,907)	(3,261)	(3,321)	(2,566)	(2,566)
Creditors	(2,907)	(3,261)	(2,566)	(2,566)	(2,566)
Short term borrowings	0	0	(755)	0	0
Long Term Liabilities	(982)	(1,820)	(4,645)	(9,645)	(14,645)
Long term borrowings	0	0	(3,235)	(8,235)	(13,235)
Other long term liabilities	(982)	(1,820)	(1,409)	(1,409)	(1,409)
Net Assets	14,484	8,797	6,284	7,304	(685)
CASH FLOW					
Operating Cash Flow	(3,163)	(4,796)	(4,403)	(2,607)	(6,528)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(4,770)	(1,805)	(6,065)	(1,805)	(1,805)
Acquisitions/disposals	0	0	0	0	0
Financing	17,873	0	3,961	4,980	0
Dividends	0	0	0	0	0
Other	0	483	(252)	(755)	0
Net Cash Flow	9,940	(6,118)	(6,759)	(187)	(8,333)
Opening net debt/(cash)	(2,468)	(10,927)	(5,139)	1,357	788
HP finance leases initiated	0	0	0	0	0
Exchange rate movements	0	0	0	0	0
Other	(1,481)	330	264	755	0
Closing net debt/(cash)	(10,927)	(5,139)	1,357	788	9,122

Source: Edison Investment Research, Crossject reports

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