EDISON

Crossject

Financial results

On track for filings next year

Pharma & biotech

Crossject recently reported FY17 results and that it remains on track for regulatory filings for several programmes in 2019, including Zeneo Sumatriptan, Midazolam, Epinephrine/Adrenaline, Hydrocortisone, and Naloxone with Terbutaline and Methotrexate in 2020. A key upcoming catalyst would be a US licensing agreement for Zeneo Sumatriptan for the treatment of acute migraine, which could come in H118.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/16	1.4	(7.3)	(0.85)	0.0	N/A	N/A
12/17	4.1	(8.5)	(0.82)	0.0	N/A	N/A
12/18e	0.0	(12.1)	(1.04)	0.0	N/A	N/A
12/19e	0.0	(12.8)	(0.98)	0.0	N/A	N/A

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

Manufacturing capabilities progressing

Crossject is continuing to improve its manufacturing capabilities, an important component of the company's ability to meet its regulatory and commercial timelines. It has been able to produce ready-to-fill sterile tubes since the end of 2017 and the production line for the gas generators has been operational since the beginning of 2018.

Sumatriptan partnership possible by H118

Crossject is in discussions to license its lead product, Zeneo Sumatriptan, for the acute treatment of migraine in the US and, according to the company, a deal is possible in H118. Ease of use and fast onset should be key selling points for the product. Additionally, a tender process for US rights to Zeneo Midazolam (which recently received orphan drug designation from the FDA) for the acute treatment of epilepsy was commenced in December of 2017.

New publication highlights the ease of use of Zeneo

In early March, the results of a human factors study in 134 healthy volunteers were published. Importantly, 93.9% could use the device without major errors (note that in previous studies of EpiPen as few as 18% of participants used the device properly), 97.0% consider the device to be easy to use and 99.3% would ask the physician for it if they were ever in need of requiring regular injections.

Valuation: €136.3m or €15.21 per share

We have increased our valuation for Crossject to €136.3m or €15.21 per basic share from €121m or €13.72 per basic share due to rolling forward our NPVs from 2017 to 2018. This was partly mitigated by a lower net cash balance and a higher share count. As of the end of 2017, the company had a cash position of €2.8m, although it raised an additional €5.25m in a convertible debt offering in February. It also announced a free allotment of warrants to existing shareholders, which could yield an additional €4.0m. Between now and projected profitability in 2020, we forecast a total funding need of €16.5m.

22 March 2018

Price	**€4.30**
Market cap	**€39m**

Net cash (€m) at 31 December 2017	0.3
Shares in issue	9.0m
Free float	80.4%
Code	ALCJ
Primary exchange	Euronext
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(4.4)	(0.47)	(14.4)
Rel (local)	(3.3)	1.8	(19.4)
52-week high/low		€6.80	€3.91

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 2020. Over the course of 2020 and 2021, Crossject expects to launch proprietary versions of six other products on its Zeneo platform.

Next events

Zeneo Sumatriptan partnership	H118

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Edison profile page

Making progress towards commercialisation

Crossject is coming closer to bringing its proprietary needle-free injection platform to commercialisation as its manufacturing capabilities are coming on line. It has been able to produce ready-to-fill sterile tubes since the end of 2017 and the production line for the gas generators has been operational since the beginning of 2018. The company is currently finalising its documentation to start producing clinical batches, which would allow it to begin clinical studies for its products.

Exhibit 1: Crossject pipeline

Product	Indication	Current expectation for submission (US/EU)	Notes
Sumatriptan	Acute migraine	2019	Bioequivalence study expected to be completed in 2018
Midazolam	Acute epilepsy seizures	2019	Bioequivalence study given regulatory go-ahead and expected to be completed in 2018
Epinephrine/Adrenaline	Anaphylactic shock	2019	Bioequivalence study expected to be completed in 2018
Methotrexate	Rheumatoid arthritis	2020	Bioequivalence study completed
Hydrocortisone	Acute adrenal insufficiency	2019	Bioequivalence study expected to be completed in 2018
Naloxone	Opioid overdose	2019	Expect to confirm formulation and pre-stability studies and receive regulatory authorisation for bioequivalence studies
Terbutaline	Severe asthma	2020	Expect to confirm formulation and pre-stability studies
Apomorphine	Parkinson's disease	2021	Expect to confirm formulation and pre-stability studies

Source: Crossject, Edison Investment Research estimates

One of the main benefits of the Zeneo platform was recently highlighted in a publication of Crossject's 134 healthy volunteer human factors study.[1] 93.9% could use the device without major errors, 97.0% consider the device to be easy to use and 99.3% would ask the physician for it if they were ever in need of requiring regular injections.

The ease of use of the Zeneo device is a major positive over other devices, including the EpiPen, which is an auto-injector. A major issue with the EpiPen is that only a minority of patients and physicians know how to use it correctly. According to one study, just 18% of participants were able to perform all steps correctly (one of the major weaknesses being not keeping the EpiPen in place for the full 10 seconds recommended).[2] In another study, 32% of participants were able to, but only 18% of paediatricians were able to correctly demonstrate use of the device.[3] With such an ease of use differential, Zeneo could become the device of choice for both patients and physicians.

Valuation

We have increased our valuation for Crossject to €136.3m or €15.21 per basic share from €121m or €13.72 per basic share due to rolling forward our NPVs from 2017 to 2018. This was partly mitigated by a lower net cash balance and a higher share count. We expect to review our valuation on completion of bioequivalence studies, as well as the announcement of partnerships, especially in the US market.

1 Allaert F. et al., *Panminerva Medica* 2018 June;60(2):52-9.

2 Sicherer S. et al., *Journal of Pediatrics* 2012 Apr;160(4):651-6.

3 Sicherer S. et al., *Journal of Pediatrics* 2000 Feb;105(2):359-362.

Exhibit 2: Crossject valuation

Product	Main Indication	Prob. of success	Launch year	WW Peak sales (€m)	Patent protection	Royalty	rNPV (€m)
Methotrexate	Rheumatoid arthritis	30%	2021	€100	2036	20%	€9.9
Sumatriptan	Acute migraine	60%	2020	€82	2036	20%	€16.4
Adrenaline	Anaphylactic shock	60%	2020	€133	2036	25% US/20% EU	€39.1
Midazolam	Acute epileptic seizures	60%	2020	€58	2036	20%	€11.3
Hydrocortisone	Acute adrenal crisis	60%	2020	€9	2036	20%	€1.3
Naloxone	Opioid overdose	60%	2020	€34	2036	20%	€7.4
Terbutaline	Severe asthma	60%	2021	€161	2036	20%	€38.9
Apomorphine	Parkinson's disease	30%	2022	€53	2036	20%	€11.8
Total							€**136.0**
Net cash (2017) (€m)							€0.29
Total firm value (€m)							€**136.28**
Total basic shares (m)							8.96
Value per basic share (€)							€**15.21**
Stock options (m)							1.52
Weighted average exercise price (€)							€3.75
Cash on exercise (€m)							€5.70
Total firm value (€m)							€141.97
Total number of shares							10.5
Diluted value per share (€)							€13.55

Source: Edison Investment Research

Financials

As of 31 December 2017, Crossject had €2.8m in cash, cash equivalents and short-term investments on hand, as well as €2.5m in long-term debt. In February, the company raised an additional €5.25m in convertible debt with a 0% coupon and a maturity date of 11 February 2020. Additionally, it announced a warrant offering for existing shareholders such that each shareholder would receive one warrant per share owned, and 10 warrants would be required to purchase an additional share (ie 10% warrant coverage). The warrants have an exercise price of €4.50 per share, which is slightly above the current share price, and if all warrants are exercised an additional €4m would be raised, although it is difficult to predict how many will be. The warrants may be exercised at any time from 10 April to 30 June 2018, so they expire relatively soon. Additionally, the company received €500,000 in repayable assistance from the French government in early 2018, with a two-year grace period.

Based on the recent results, we have increased our operating spending estimates by approximately €0.9m in 2018 (due to slightly higher R&D and SG&A expenditures). Between now and projected profitability in 2020, we forecast a total funding need of €16.5m, which does not take into account any funding received from the warrant offering to existing shareholders. This requirement could be further mitigated somewhat by additional upfront payments from partners, as well as milestone payments on product approvals.

Exhibit 3: Financial summary

€000s	2015	2016	2017	2018e	2019e
Year end 31 December	French GAAP	French GAAP	French GAAP	French GAAP	French GAAP
PROFIT & LOSS					
Revenue	2,370	1,427	4,142	0	0
Cost of Sales	(0)	0	0	0	0
Gross Profit	2,369	1,427	4,142	0	0
R&D Expenses	(3,077)	(4,384)	(7,186)	(8,264)	(8,760)
SG&A and Other Expenses	(4,808)	(2,630)	(3,321)	(3,587)	(3,520)
EBITDA	(5,516)	(5,587)	(6,365)	(11,851)	(12,280)
Operating Profit (before amort. and except.)	(7,013)	(7,291)	(8,621)	(11,851)	(12,280)
Intangible Amortisation	0	0	0	0	0
Other	0	0	0	0	0
Exceptionals	0	0	0	0	0
Operating Profit	(7,013)	(7,291)	(8,621)	(11,851)	(12,280)
Net Interest	(19)	(38)	159	(294)	(493)
Other	299	(429)	(278)	0	0
Profit Before Tax (norm)	(6,720)	(7,329)	(8,462)	(12,145)	(12,773)
Profit Before Tax (FRS 3)	(6,732)	(7,758)	(8,740)	(12,145)	(12,773)
Tax	1,045	1,095	1,129	2,479	2,628
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	(5,675)	(6,234)	(7,333)	(9,666)	(10,145)
Profit After Tax (FRS 3)	(5,687)	(6,663)	(7,611)	(9,666)	(10,145)
Average Number of Shares Outstanding (m)	6.7	7.3	9.0	9.3	10.3
EPS - normalised (€)	(0.86)	(0.85)	(0.82)	(1.04)	(0.98)
EPS - FRS 3 (€)	(0.86)	(0.91)	(0.85)	(1.04)	(0.98)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	5,936	9,252	11,418	14,353	14,460
Intangible Assets	2,330	2,506	4,057	4,057	4,057
Tangible Assets	1,727	5,636	5,471	8,406	8,513
Other	1,878	1,109	1,890	1,890	1,890
Current Assets	7,943	4,997	6,298	5,947	5,757
Stocks	761	398	1,201	1,201	1,201
Debtors	1,991	1,966	2,291	2,291	2,291
Cash	5,139	2,634	2,806	2,455	2,265
Other	52	0	0	0	0
Current Liabilities	(3,261)	(3,321)	(4,273)	(4,273)	(4,273)
Creditors	(3,261)	(2,566)	(4,273)	(4,273)	(4,273)
Short term borrowings	0	(755)	0	0	0
Long Term Liabilities	(1,820)	(4,645)	(7,358)	(19,608)	(29,671)
Long term borrowings	0	(3,235)	(2,517)	(14,767)	(24,767)
Other long term liabilities	(1,820)	(1,409)	(4,841)	(4,841)	(4,904)
Net Assets	8,797	6,284	6,085	(3,581)	(13,727)
CASH FLOW					
Operating Cash Flow	(4,796)	(4,403)	(4,974)	(8,353)	(8,065)
Net Interest	0	0	0	0	0
Tax	0	0	0	0	0
Capex	(1,805)	(6,065)	(4,248)	(4,248)	(2,124)
Acquisitions/disposals	0	0	0	0	0
Financing	0	3,961	7,412	0	0
Dividends	0	0	0	0	0
Other	483	(252)	3,285	0	0
Net Cash Flow	(6,118)	(6,759)	1,475	(12,601)	(10,189)
Opening net debt/(cash)	(10,927)	(5,139)	1,357	(289)	12,312
HP finance leases initiated	0	0	0	0	0
Exchange rate movements	0	0	0	0	0
Other	330	264	170	0	0
Closing net debt/(cash)	(5,139)	1,357	(289)	12,312	22,502

Source: Company accounts, Edison Investment Research

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