

Spotlight - Update

Adocia

First arbitration won; partners sought

The Arbitration Panel has found for Adocia in the first phase of the ongoing arbitration against Lilly; Adocia will be awarded \$11.6m in damages. On the partnering front, Adocia has struck a deal with Tonghua Dongbao (THDB) that includes BioChaperone (BC) Combo and BC Lispro for China and additional undisclosed countries. The deal includes a \$50m upfront payment, up to \$85m in milestone payments and double-digit royalties on net sales. A Phase I clinical trial with BC Pramlintide Insulin is ongoing; Adocia plans to start Phase I trials with BC Glucagon GLP-1 and GLP-2 in H119. Finally, it presented six abstracts at the American Diabetes Association meeting. Gross cash at end-H118 was €55.8m.

Adocia wins first phase of arbitration against Lilly

Adocia is due to receive \$11.6m from Lilly after the Arbitration Panel decided in its favour for specific relief due to Lilly's change of development plan. Adocia also seeks interests and reimbursement of the legal expenses. A hearing on the second phase of the arbitration proceed is scheduled for December 2018, with a decision in 2019 vs Q318 before. This case is related to the misappropriation, improper use and breach of confidential information and Adocia's discoveries by Lilly. Adocia has recently updated the amount of damages and other relief to over \$1.8bn (vs \$200m before), based on its own valuation of the damages. Lilly has filed counterclaims for c \$188m, claiming Adocia hid its discoveries and confidential information. We view this first decision as positive, although we are cautious on the second as the claims are different, and see a settlement as a potential scenario. If the second arbitration is favourable for Adocia, it could provide the funds to fully develop BC Lispro.

BC Combo and BC Lispro get China partner

The deal with THDB provides a cash boost for Adocia, pocketing an upfront payment of \$50m, of which \$40m pertains to BC Combo and \$10m to BC Lispro. Adocia can receive an additional \$85m (\$50m for BC Combo and \$35m for BC Lispro). Finally, Adocia may receive double-digit royalties on net sales of the products. As described in our initiation report, pre-mixed insulins are best-sellers in emerging markets like China. Adocia retains rights in the territories not covered by this agreement, including the US, Europe, Japan and other countries. The company continues to look for a global partner for BC Lispro outside China.

Valuation: EV of €68m indicates room for upside

Adocia's market cap is c €116m and its enterprise value (EV) is almost €68m based on last reported net cash of €48.0m, the lowest of its peers. Pipeline progression and partnerships are the main value drivers.

Consensus estimates							
Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)	
12/16	30.4	(8.0)	(1.2)	0.0	N/A	N/A	
12/17	27.2	(8.2)	(1.2)	0.0	N/A	N/A	
12/18e	39.1	7.2	0.07	0.0	N/A	N/A	
12/19e	26.1	5.4	(0.9)	0.0	N/A	N/A	

Source: Bloomberg

Pharma & biotech

5 September 2018





Share details

Code	ADOC
Listing	Euronext Paris
Shares in issue	6.91m
Net cash (€m) as at 30 June 2018	48.0

Business description

Adocia is a French biotech company focused on innovative formulations of approved proteins. The company features the BioChaperone technology platform, which has generated six products in clinical stage; the most advanced is BioChaperone Lispro, which is Phase III-ready. Adocia has four preclinical products; three are due to start clinical trials in 2018.

Bull

- Proprietary versatile technology platform.
- Clinical-stage pipeline addressing the large diabetes market.
- Proven safety in over 17 clinical trials.
- Deal with THDB.

Bear

- Need of partnerships to advance to late stage.
- Competition from large pharma companies.
- Uncertainty regarding litigation against Lilly.

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BC technology at the core of its pipeline

Adocia has made progress with its pipeline over the past few months. Early this year, the company announced positive data from a dose-proportionality Phase I study with BC Combo in type 2 diabetes patients. In April 2018 the company initiated a first-in-man trial with BC Pramlintide Insulin in 24 type 1 diabetes subjects. Data are expected in Q318. Furthermore, the deal with THDB will help continue the development of BC Combo and BC Lispro in China and other territories. Exhibit 1 shows Adocia's projects.

Exhibit 1: Pipeline						
Product	Indication	Stage	Comments			
BioChaperone Lispro	T1D and T2D	Phase III-ready	Partnered in China and other undisclosed countries Available for partnering RoW			
BioChaperone Combo	T1D and T2D	Five Phase I/IIb trials completed	Partnered in China and other undisclosed countries Available for partnering RoW			
BioChaperone Glucagon	Hypoglycaemia	Phase I trial completed	To advance into further development			
HinsBet	T1D and T2D	Phase I/II completed	Looking for partners in emerging markets			
BioChaperone Pramlintide Insulin	T1D	Phase I ongoing	Top-line results in Q318			
BioChaperone Glucagon GLP-1	Obesity	Preclinical	Start clinical trial in H119			
BioChaperone GLP-2	SBS	Preclinical	Start clinical trial in H119			

Furthermore, Adocia presented six abstracts at the American Diabetes Association Scientific Sessions in June 2018. The abstracts showed follow-up data and further findings from previous clinical and preclinical studies. Exhibit 2 shows the abstracts' titles and comments.

Exhibit 2: American Diabetes Association 2018 Scientific Sessions data				
Abstract title	Comments			
BioChaperone Glucagon, a stable ready-to-use liquid glucagon formulation, is well tolerated and quickly restores euglycemia after insulin-induced hypoglycemia.	Follow-up data from the Phase I study in 27 patients comparing two formulations of BC Glucagon to Novo Nordisk's Glucagen (link).			
BioChaperone technology enables the development of pramlintide-prandial insulin combinations.	In vitro and pharmacodynamics properties of BC Pramlintide for clinical development (link).			
Pooled analysis of clinical trials investigating the pharmacokinetics (PK) of ultra-rapid insulin BioChaperone Lispro versus Lispro in subjects with type 1 and type 2 diabetes.	Pooled analysis of four Phase I clinical trials with BC Lispro, confirms faster onset and offset vs conventional Lispro (link).			
Better postprandial glucose (PPG) control with BioChaperone Combo (BC Combo) than with Lispro Mix25 (LMx) or separate Glargine & Lispro (G+L) administration in subjects with type 2 diabetes.	Data from a Phase I trial in 39 subjects. BC Combo had superior PPG control with fewer hypoglycaemia events compared to both LMx and Lantus+Humalog (link).			
BioChaperone 222 (BC222), the new excipient enabling the ultra-rapid BioChaperone Lispro formulation, is completely absorbed and rapidly excreted after subcutaneous injection.	Investigated PK properties of the BC222 excipient. BC222 was completely absorbed after subcutaneous injection and quickly excreted by the kidneys (link).			
The ultra-rapid insulin BioChaperone Lispro shows favorable pharmacodynamics (PD) and pharmacokinetics (PK) vs faster aspart (FIA) and insulin aspart (ASP) in insulin pumps.	PK and PD data from Phase I trial in 43 patients vs Novolog and Fiasp. BC Lispro showed faster PK/PD profiles than Fiasp. BC Lispro had shorter duration of action than Novolog (link).			
Source: Adocia, Edison Investment Research				

We believe the BC technology has demonstrated the potential of its mode of action in a number of small, Phase I/II trials.

Financials: H118 results released

Adocia's revenues in the first half of the year were €36.1m (vs c €23.1m in H117), mainly due to the partial recognition of €32.8m from the upfront payment of \$50m (€41.1m) received from THDB. Additional revenue of €3.3m corresponds to grants, public financing and research tax credits.

Operating expenses increased by €6m from €15.8m in H117 to €21.8m in H118. This was mainly related to litigation expenses in the arbitration procedures against Lilly (€3.2m) and personnel expenses (€2m). Around 60% of expenses were associated with research and development activities, or c 75% excluding the legal expenses, as opposed to 80% in H117.



Net result for H118 was a profit of €10.6m vs a profit of €7m in H117 (which would have been a net loss of €6.3m excluding the impact of the deal termination with Lilly).

From the balance sheet, we highlight a cash position of €56m in H118 vs €35m at end-2017. The cash position includes the upfront payment from THDB of €37.1m, net of taxes. Financial debt of €7.9m mainly relates to a 2016 loan to finance the acquisition of the company's headquarters and research facilities. Financial debt increased by €0.5m, due to dollar credit lines for the litigation expenses, offset by repayment of part of the loan.

Excluding the upfront payment from THDB, Adocia consumed approximately €16m in cash for operations. The main sources of cash for the company are potential new partnerships, milestone payments from THDB, the decision on the legal cases against Lilly and equity/debt financings.

Exhibit 3: Financial summary				
Year-end 31 December (€m)	2015	2016	2017	H118
Income statement				
Revenue	44.8	30.4	27.2	36.1
Profit before tax (as reported)	12.2	(7.8)	(8.5)	10.6
Net income (as reported)	12.6	(7.9)	(8.6)	10.6
EPS (as reported) (€)	1.8	(1.2)	(1.2)	1.5
Dividend per share (€)	0.0	0.0	0.0	0.0
Balance sheet				
Total non-current assets	2.1	8.8	9.1	8.7
Total current assets	86	70	44.7	73.2
Total assets	88.1	78.8	53.8	81.9
Total current liabilities	20.4	28	8.8	23.4
Total non-current liabilities	20.6	8	8.0	10.4
Total liabilities	41	36	16.8	33.9
Net assets	47	42.8	37.0	48.0
Shareholders' equity	47	42.8	37.0	48.0
Cash flow statement				
Net cash from operating activities	(6.2)	(13.1)	(22.2)	20.9
Net cash from investing activities	(0.8)	(7.2)	(1.7)	(0.4)
Net cash from financing activities	29.3	6.3	0.7	0.6
Net cash flow	22.3	14	23.3	(21.1)
Cash and cash equivalent end of period	72.1	58	34.8	55.9
Source: Adocia accounts. Note: Figures are	rounded.			

Valuation

We estimate that Adocia's lead product, BC Lispro, targets a \$6.5bn market, while BC Combo could be close to a \$4.5bn market, based on sales of current products. According to Adocia, in 2016, the worldwide pre-mix insulin market was \$5bn and the hypoglycaemia rescue market was \$300m. Although it is early stage, BC Glucagon GLP-1 also targets the obesity market. According to Evaluate Pharma, sales of the top 10 obesity products were c \$1bn in 2017, expected to grow to \$1.8bn in 2022.

Adocia's market cap is c €122m and its EV is almost €74m, based on the last reported net cash balance of €48.0m. Compared to its peers, Adocia has the lowest EV in the group (Exhibit 4). All these companies are at different stages of development, with multiple other assets in the pipeline, which complicates any peer group comparison. Moreover, relative valuation metrics, such as P/E, are difficult to assess given the early-stage and often loss-making nature of these companies.

We think the market is expecting large pivotal clinical trials conducive to market approval. We believe a clearer development and regulatory path, in the form of a partnership or available resources to conduct such pivotal trials, could be supportive of Adocia's shares.



	Market cap	EV				
Company	(m)	(m)	Lead product	Status	Rest of pipeline	Comments
MannKind Corp	\$170	\$266	Afrezza	Market	Phase II for paediatric T1D	Sold \$9m in 2017
Poxel	€173	€117	Imeglimin oral	Phase IIb EU/US/Ot hers	Phase I for NASH and hepatitis B	Partners: Dainippon, Roivant, Enyo
Zealand Pharma	\$429	\$368	Dasiglucagon rescue	Phase III	Phl/II:Dasiglucagon/Glepa glutide/GLP-2/GLP1+gcg	Partnered with Boehringer Ingelheim
Tonghua Dongbao	CNY35,116	CNY34,750	Gansulin	Market	1 Phase II, 3 preclinical products	Adocia's partner for BC Lispro and BC combo in China + additional undisc. countries.
Adocia	€122	€74	BC Lispro	Phase III- ready	Phase I/II BC pipeline	To start three clinical trials in 2018

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