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MOR prospects of a deal

Pharma & biotech

The initial data from the Phase Ib/IIa trial in rheumatoid arthritis (RA) with MOR103 increase the likelihood that MorphoSys can partner the product ahead of the Phase Ib trial in multiple sclerosis (MS). In the study, a strong efficacy signal with early onset of action was detected at all doses tested and the product was well tolerated, suggesting that MOR103's activity compares favourably to that of RA treatments. More data from the study could be reported at the ACR meeting in November. We have raised our valuation from €659m to €697m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/10	87.0	17.9	59.2	0.0	40.4	N/A
12/11	100.8	21.9	72.3	0.0	33.0	N/A
12/12e	75.2	4.4	16.4	0.0	145.5	N/A
12/13e	79.2	8.5	31.2	0.0	76.6	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation and exceptional items.

Impressive initial data on MOR103

Initial results from the Phase Ib/IIa trial in RA with MOR103, which inhibits GM-CSF activity, showed that at the ACR20 score improvements at week four compared to placebo were 17.6 with dosing of 0.3mg/kg, 60.8 with 1.0mg/kg and 23.0 with 1.5mg/kg. These efficacy levels are similar or better than that seen in clinical trials with the main approved treatments for RA. MOR103 was also well tolerated at all doses.

More data expected in Q412

MorphoSys is submitting a late-breaking abstract for the ACR meeting in November, where it hopes to present more results. During the Phase Ib/IIa trial, other efficacy scores (ACR50, DAS28, EULAR) and changes in biomarkers were measured, and MRI analysis was conducted. Phase Ib data with a subcutaneous formulation should be reported soon, the Phase Ib/IIa trial used intravenous administration.

Increased prospect of major licensing deal

MorphoSys aims to partner MOR103 with the data from this trial. Despite the promising data, it is not a foregone conclusion as RA is a very competitive space with over 30 biologic products on the market or in late-stage clinical trials. However, the strength of the data, the fact that MOR103 has three mechanisms of action (most only have one) and its potential in MS (Phase Ib data expected in H213) count in its favour. Two reference deals for a partnering are Abbott's in-licensing of tregalizumab from Biotest ($480m deal) and of GLPG0634 from Galapagos (>$1bn deal).

Valuation: DCF valuation of €697m

We have increased our valuation by €38m to €697m, mainly because of the Phase Ib/IIa results. We have revised estimates and MorphoSys remains on track to achieve FY12 revenue guidance of €75-80m, but it will need to earn significant milestones or sign major alliance deals in Q412 as no milestones or deals were announced in Q312.

MorphoSys is a research client of Edison Investment Research Limited

4 October 2012

Price	€23.9
Market cap	€552m

Shares in issue	23.1m
Free float	70%
Code	MOR
Primary exchange	Frankfurt
Other exchanges	N/A

Share price performance

%	1m	3m	12m
Abs	22.5	37.5	21.3
Rel (local)	18.4	17.5	(6.3
52-week high/low		€24.2	€15.9

Business description

MorphoSys is a German biotechnology company. It uses its proprietary technologies to develop human antibodies for therapeutic use. It also develops diagnostic antibodies and sells antibodies for use in research.

Next events

Q312 results	7 November 2012
ACR conference	9-14 November 2012

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Update: MOR103 data raises prospects of a deal

Initial data from a Phase Ib/IIa trial with MorphoSys' lead proprietary compound, MOR103 (Exhibit 1), indicates that it has significant potential as a treatment of RA. The company hopes that a late-breaking abstract will be accepted for the ACR (American College of Rheumatology) meeting in November so that more data from the trial can be presented there. The results published so far are impressive and should result in major pharmaceutical companies being interested in licensing the product. However, the RA market is very competitive, making the task of partnering MOR103 more challenging. MOR103 is in a Phase Ib trial in MS, MorphoSys does not plan to wait for these results to license it, but the potential in this other major indication should help it find a partner. We have increased our valuation to €697m.

Exhibit 1: Proprietary clinical R&D pipeline

Product (target)	Development stage (Indication)	Notes
MOR103 (GM-CSF)	Phase II (rheumatoid arthritis, multiple sclerosis)	Completed Phase Ib/IIa trial in active RA (four doses of placebo, 0.3, 1.0, 1.5mg/kg iv, n=92, double-blind), MOR103 was well tolerated and showed strong efficacy signal (ACR20 improvements at 4 weeks was 17.6 with 0.3mg/kg, 60.8 with 1.0mg/kg and 23.0 with 1.5mg/kg). Primary endpoint is adverse event rate and safety; secondary endpoints are various efficacy measures; data expected in Q312. Phase Ib trial in multiple sclerosis (four doses of placebo, 0.5, 1.0, 2.0mg/kg iv, n=30, double-blind), primary endpoint: incidence and severity of adverse events; data expected in H213. A Phase I study with a sub-cutaneous formulation is expected to report data in Q412. Phase I (n=63) successfully completed.
MOR208 / Xmab5574 (CD19)	Phase I (chronic lymphocytic leukaemia, B-cell acute lymphoblastic leukaemia, non-Hodgkin's lymphoma)	Phase I trial in CLL/SLL (small lymphocytic lymphoma; n=30, dose escalation study, open label). Endpoints are maximum tolerated dose, safety, efficacy, PK and PD data and preliminary anti-tumour activity. Trial is completed and data are expected in Q412. Phase II study in B-ALL (n=30) is due to start in December 2012, primary endpoint is overall response rate. Phase II study in NHL (n=120) is due to start in December 2012, primary endpoint is overall response rate. MorphoSys in-licensed MOR208 from Xencor for an upfront payment of $13m, milestone payments and royalties. Agreement with Boehringer Ingelheim to manufacture MOR208 for use in clinical trials and to provide a commercial supply potentially.
MOR202 (CD38)	Phase I/II (multiple myeloma)	Phase I/II dose escalation trial in multiple myeloma in combination with bortezomib and lenalidomide (open label, n=82). Endpoints are maximum tolerated dose, safety, efficacy, PK and PD data and overall response rate, estimated primary completion date is November 2014. Multiple myeloma tumour cells express CD38 in c 98% of patients. Preclinical data shows MOR202 acts synergistically with lenalidomide and bortezomib.

Source: Edison Investment Research

Phase Ib/IIa data on MOR103

The Phase Ib/IIa trial with MOR103 in RA showed that the product was well tolerated and has promising activity levels. The trial was a randomised, double-blind placebo controlled trial with 96 patients with active mild to moderate RA (DAS28≤5.1, disease activity score). It compared the effects of four weekly doses of MOR103 (0.3, 1.0 and 1.5mg/kg) with those of placebo. MorphoSys decided to assess MOR103's activity in the mild to moderate setting as most patients seen in daily clinical practice have this level of disease activity.

The trial was well balanced with equal distribution for all major demographic parameters and the mean DAS28 scores between 4.7 and 4.9 in placebo and treatment groups. 26 patient centres were used and 64-79% of patients were on a stable regimen of concomitant DMARD therapy. There was a low placebo effect (Exhibit 2), which also suggests that the trial was well run.

The ACR20 data from the Phase Ib/IIa trial suggests that MOR103 has significant activity with a rapid onset of action. The trial is only a relatively small trial (n=96), however, reassuringly an effect was seen at all doses.

Exhibit 2: ACR20 responses at week 4 (n=96)

Treatment arm	Number of patients	ACR20 response (%)*	Improvement in ACR20 compared to placebo (%)	Significance
Placebo	27	7.4	N/A	N/A
0.3mg/kg	24	25.0	17.6	N/A
1.0mg/kg	22	68.2	60.8	p<0.0001
1.5mg/kg	23	30.4	23.0	N/A

Source: MorphoSys. Note: * ACR20 describes the percentage patients who achieved a 20% improvement in tender or swollen joint counts as well as 20% improvement in three other disease-relevant criteria.

There was a particular strong efficacy signal in the 1.0mg/kg arm; surprisingly it was greater than in the 1.5mg/kg arm. It is difficult to explain from a theoretical point of view why the 1.0mg/kg dose could be more effective than the 1.5mg/kg dose; at this stage we would be cautious about over interpreting this apparent dosing effect and believe it is probably a statistical effect caused by the limited number of patients in each arm.

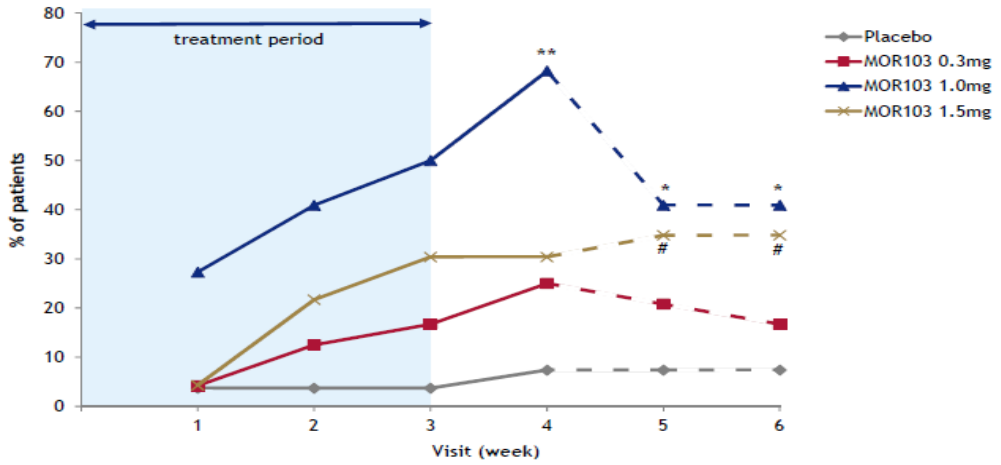
An ACR20 effect was detected after only one dose in the 1.0mg/kg arm and after two weeks in the other treatment arms (Exhibit 3). There is limited data on the early response of other RA drugs (tested in the moderate to severe setting) and the rates of placebo responses are variable (Exhibit 4). However, the Phase Ib/IIa data suggests that MOR103's onset of action and level of activity compare favourably with that of drugs approved for rheumatoid arthritis. The activity of MOR103 also appears comparable to mavrilizumab, a monoclonal antibody being developed by AstraZeneca and has a similar mechanism of action to MOR103 (it inhibits the GM-CSF receptor instead of GM-CSF).

A robust efficacy signal was detected until six weeks in the arms with the two higher doses, three weeks after the last dose of MOR103 was received (effect tailed off after week six). This suggests that bi-monthly dosing or monthly dosing with MOR103 should be efficacious, in line with recently approved TNFα inhibitors (certolizumab pegol [Cimzia] and golimumab [Simponi]). Different dosing schedules will have to be tested in subsequent trials, probably using the subcutaneous formulation that is currently being studied in a Phase I trial (results due in Q412).

MOR103 was well tolerated in the Phase Ib/IIa trial. Fewer patients suffered adverse events (AE) in the treatment arms (12.5%) than in the placebo arm (25.9%) – most common AEs were nasopharyngitis, RA flare, fatigue, and hypertension as seen in most RA clinical trials. There were two serious AEs (paronchia and pleurisy) in the MOR103 arms, but these were not treatment related and there were no severe AEs in these arms. No changes in pulmonary function occurred and only one person, who was in the placebo arm discontinued treatment because of an AE.

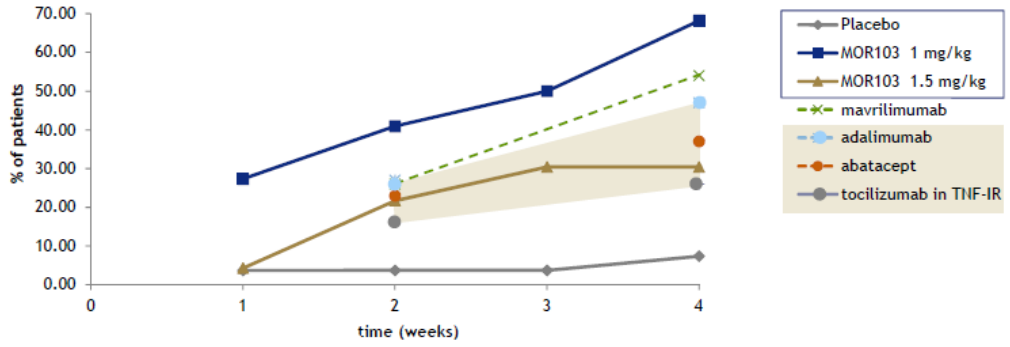
MorphoSys is yet to release all of the data from the trial. It is submitting a late-breaking abstract for the ACR meeting from 10-14 November and hopes to present the full data at this conference. The additional results that could be presented include other efficacy measures, such as: ACR50, DAS28, EULAR scores, biomarker data and MRI analysis (RAMIS score).

Exhibit 3: ACR20 response over six weeks with MOR103



Source: MorphoSys; Note: n=96; **p<0.0001; *<0.05; p~0.07

Exhibit 4: ACR20 response over four weeks with MOR103 and other RA drugs



Source: MorphoSys

Potential partnering of MOR103

MorphoSys now aims to out-license MOR103 and is talking to several potential partners. However, it is not a foregone conclusion that MorphoSys will be able to do so on attractive economic terms. RA is a highly competitive field (over 30 biologic products are on the market, or in Phase II or III clinical trials and they target c 20 different mechanisms of action, see note dated 7 June). Also new oral therapies such as tofacitinib are expected to launched soon and the cost of development is high (>$150m) due to the large clinical trials that are required. However, the RA market for biological products is very large (>$15bn), the impressive data from the Phase I/II study is supported by robust science and MOR103 has potential in MS and pain relief associated with inflammation and arthritis, therefore there should be significant interest in MOR103 from large pharmaceutical companies.

In RA, potential partners could be interested in MOR103 because it targets RA through more than one mode of action. MOR103 inhibits macrophage activity like other biologic RA treatments, which have been approved (TNFα and IL-6 pathway inhibitors); but it also prevents activation of cells with a myeloid cell lineage (neutrophils and antigen-presenting dendritic cells) and suppresses development of Th17 cells (a subset of T-cells associated with inflammation) unlike these other drugs. So MOR103 might be more effective at controlling the progression of RA than existing biologic treatments and the data from the Phase Ib/IIa indicates that this might be the case.

In MS, preclinical studies have demonstrated MOR103's potential and a paper in Nature Immunology indicates that GM-CSF (the target of MOR103) plays a key role in the progression of the disease. MorphoSys is conducting a Phase Ib study (n=30), which should be completed in H213, but it will not wait for these results to partner the product.

Preclinical studies, recently published in three journals (*Annals of the Rheumatic Diseases*, *Nature Reviews Rheumatology* and *Arthritis Research & Therapy*) indicate that GM-CSF plays an important role in the mediation of pain. Thus, MOR103 might have potential in osteoarthritis as well.

The reference deals for any partnering agreement with MOR103 will probably be the licensing deals with tregalizumab and GLPG0634 (Exhibit 4). There is less clinical data on MOR103 than there was on tregalizumab and Galapagos benefited from the interest in Pfizer's toficitinib (a JAK1/3 inhibitor), which should soon be approved. But in MOR103's favour, it has blockbuster potential in two distinct indications, the intellectual property covering the targeting of GM-CSF in autoimmune diseases and the new Phase Ib/IIa data.

Exhibit 5: Recent licensing deals with RA products

Product (partners)	Product details	Deal terms	Development status at time of signing
tregalizumab / BT-061 (licensed by Biotest to Abbott)	Monoclonal antibody against CD4 (activates regulatory) T-cell	Date: June 2011 Upfront payment: $85m Potential milestones: $395m Royalties: undisclosed Co-promotion: Germany, France, UK, Italy and Spain Development costs: Abbott all costs	Phase IIb (n=176) initiated in RA Phase II (n=110, +MTX) in RA – Data with 50mg/week: Δ ACR50 16%, Δ ACR70 9% at week 9. Phase IIa (n=96, monotherapy) in RA – Data with 50 and 100mg/week (n=25): Δ ACR20 27%, Δ ACR50 23%, Δ ACR70 7% at week 7. Phase II (n=48) in psoriasis: Trial ongoing Phase I/IIa (n=55) in psoriasis: Data with 25mg/week (best response) Δ PASI50 35%, Δ PASI75 20%. Phase I (n=57) in healthy volunteers
GLPG0634 (licensed by Galapagos to Abbott)	Oral JAK1 inhibitor (inhibits signalling mechanism used by many cytokines)	Date: February 2012 Upfront payment:$150m* Licensing fee: $200m if Ph II studies meet pre-specified criteria Potential milestones: $1.0bn Royalties: tiered double-digit Co-promotion: Benelux countries Development costs: Galapagos until end of Ph II, Abbott all Phase III costs	Phase IIa (n=36) in RA: Data with 100 bid and 200mg QD: Δ ACR20 50.0% at week 4, p<0.01 Phase I (n=32) in healthy volunteers: safe and well tolerated up to 200mg QD for 8 days.

Source: Edison Investment Research. Note: *c $55m net of expected Phase II costs; Δ ACR20, Δ PASI50 are the improvements in activity score indexes in RA and psoriasis, respectively, detected in the treatment arms compared to placebo arms; MTX is methotrexate; QD is daily dosing; bid is twice daily dosing.

Financials and valuation

We have increased our valuation of MorphoSys by €38m to €697m (€13.13 per share), having increased the likelihood of MOR103 achieving peak sales of $1.2bn in RA from 25% to 30%, adjusted our forecasts following MorphoSys's Q212 results (Exhibit 6) and changed discount factors because of the progression of time. A full breakdown of our other valuation assumptions are detailed in our note dated 7 June. We have only made a modest change to our risk adjustment for MOR103 in RA as we are waiting to see the full data from the Phase Ib/IIa trial and also the further development of the product does depend on MorphoSys being able to partner it.

Exhibit 6: Summary of changes to estimates

	Sales			PBT			EPS		
	Old	New	% change	Old	New	% change	Old	New	% change
2012e	75.3	75.2	(0.1)	5.5	4.4	(20.0)	21.2	16.4	(22.6)
2013e	79.7	79.2	(0.6)	8.3	8.5	2.8	30.5	31.2	2.2

Source: Edison Investment Research. Note: Figures in €m, except per share data.

MorphoSys has maintained its guidance for the full year (revenues of €75-80m; proprietary R&D of €20-25m; and EBIT of €1-5m) and we continue to forecast that this will be achieved. We have reduced our adj PBT largely because of a lower than expected margin on its partnered discovery operations in H112. However, this will probably depend on the company having a strong Q4, in which it earns significant milestones or enters into new alliances. In Q312, no milestones or new collaborations have been announced so that the results for the quarter will probably be similar to those achieved in Q212. MorphoSys will be reporting its Q312 results on 7 November.

Exhibit 7: Financial summary

€'000s	2009	2010	2011	2012e	2013e	2014e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	**81,024**	**87,036**	**100,777**	**75,224**	**79,221**	**85,071**
Cost of Sales	(6,744)	(7,284)	(7,024)	(7,331)	(7,411)	(7,651)
Gross Profit	74,280	79,752	93,753	67,893	71,810	77,420
EBITDA	**16,751**	**15,969**	**18,787**	**6,920**	**8,055**	**9,988**
Operating Profit (before GW and except.)	**15,122**	**13,834**	**20,496**	**3,293**	**7,116**	**8,985**
Intangible Amortisation	(3,720)	(3,985)	(8,338)	(2,238)	(4,127)	(3,861)
Exceptionals/Other	0	0	0	0	0	0
Operating Profit	**11,402**	**9,849**	**12,158**	**1,054**	**2,989**	**5,124**
Net Interest	1,992	4,089	1,412	1,089	1,411	1,450
Other	(360)	(767)	(2,139)	0	0	0
Profit Before Tax (norm)	**17,114**	**17,923**	**21,908**	**4,382**	**8,527**	**10,435**
Profit Before Tax (FRS 3)	**13,034**	**13,172**	**11,430**	**2,143**	**4,400**	**6,574**
Tax	(4,070)	(3,975)	(3,214)	(597)	(1,320)	(1,972)
Deferred tax	0	0	0	0	0	0
Profit After Tax (norm)	**13,044**	**13,948**	**18,694**	**3,785**	**7,207**	**8,462**
Profit After Tax (FRS 3)	**8,964**	**9,196**	**8,216**	**1,546**	**3,080**	**4,602**
Average Number of Shares Outstanding (m)	22.5	22.7	22.9	23.0	23.1	23.1
EPS - normalised (c)	56.5	59.2	72.3	16.4	31.2	36.6
EPS - FRS 3 (c)	39.9	41.6	35.9	6.7	13.3	19.9
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0	0.0
Gross Margin (%)	91.7	91.6	93.0	90.3	90.6	91.0
EBITDA Margin (%)	**N/A**	**18.3**	**18.6**	**9.2**	**10.2**	**11.7**
Operating Margin (before GW and except.) (%)	N/a	N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets	**50,499**	**80,047**	**73,718**	**70,526**	**68,234**	**66,346**
Intangible Assets	44,109	69,208	66,028	62,807	59,869	57,284
Tangible Assets	4,997	6,190	6,106	6,045	6,691	7,389
Other	1,394	4,649	1,583	1,673	1,673	1,673
Current Assets	**155,592**	**132,506**	**154,693**	**159,281**	**166,595**	**175,936**
Stocks	3,990	4,135	3,281	4,017	4,061	4,192
Debtors	11,157	15,009	12,203	12,366	13,023	13,984
Cash	135,139	108,422	134,365	138,654	145,268	153,515
Other	5,306	4,939	4,843	4,244	4,244	4,244
Current Liabilities	**(24,252)**	**(21,351)**	**(23,751)**	**(21,629)**	**(21,837)**	**(24,171)**
Creditors	(24,252)	(21,351)	(23,751)	(21,629)	(21,837)	(24,171)
Short term borrowings	0	0	0	0	0	0
Long Term Liabilities	**(7,904)**	**(5,281)**	**(7,524)**	**(7,667)**	**(7,800)**	**(7,916)**
Long term borrowings	(33)	(128)	(74)	(74)	(74)	(74)
Other long term liabilities	(7,871)	(5,153)	(7,451)	(7,593)	(7,726)	(7,842)
Net Assets	**173,934**	**185,922**	**197,136**	**200,511**	**205,191**	**210,195**
CASH FLOW						
Operating Cash Flow	**(2,141)**	**4,571**	**28,564**	**6,700**	**10,081**	**10,847**
Net Interest	(281)	121	358	745	1,411	1,450
Tax	1,443	(2,160)	(1,852)	(2,056)	(2,106)	(1,072)
Capex	(3,810)	(13,810)	(3,453)	(2,460)	(2,773)	(2,977)
Acquisitions/disposals	0	(18,096)	0	0	0	0
Financing	1,546	2,836	1,377	209	0	0
Dividends	0	0	0	0	0	0
Other	(126)	(640)	0	805	0	0
Net Cash Flow	(3,369)	(27,178)	24,994	3,943	6,613	8,248
Opening net debt/(cash)	**(137,817)**	**(135,106)**	**(108,295)**	**(134,291)**	**(138,581)**	**(145,194)**
HP finance leases initiated	0	0	0	0	0	0
Exchange rate movements	(91)	(51)	(177)	(184)	0	0
Other	749	418	1,178	530	(0)	0
Closing net debt/(cash)	**(135,106)**	**(108,295)**	**(134,291)**	**(138,581)**	**(145,194)**	**(153,442)**

Source: Edison Investment Research, company accounts