Galapagos (GLPG NA)

Overweight

Price:€89.78

24 Oct 2018

Solid Q3. Restructuring of Cystic Fibrosis collaboration removes an overhang and frees up cash to invest in the pipeline

Last night after the market close Galapagos (GLPG) announced (1) the topline results of the Phase II FALCON study in Cystic Fibrosis (CF), (2) the restructuring of the CF agreement with AbbVie, and (3) 3Q'18 results. On FALCON, the initial doublet combination demonstrated a mean increase in ppFEV1 of c.3%. However, the addition of a third agent (C2 corrector GLPG2737) did not enhance the activity of the doublet combination, and so this triple combination does not seem competitive vs. data seen from Vertex. Given the results of the PELICIAN study, we were cautious into the FALCON read out and hence we did not include any value in our model. With the restructuring of the CF agreement, GLPG no longer have to fund development of the combination and they will receive $45m upfront, up to $200m milestones and tiered royalties on net sales of CF assets. Given the fairly weak FALCON data and no further investment in CF required, we see the restructuring as a positive for GLPG, which has been a bear point and an overhang for the shares, in our view. 3Q'18 results were solid, with total revenue and other income of €103.2m, a 92% beat vs. Bloomberg (BBG) Consensus of €53.9m (n = 5) (97% beat vs. JPMe €52.4m – due to full recognition of the €47.5m upfront from NOVN collaboration, JPMe only partial recognition), and Operating Profit of €12.3m vs. BBG Consensus operating loss of -€46.5m (n = 6) mainly benefitting from the €47.5m upfront payment. As a result, basic EPS of €0.29 also came in above BBG Consensus of -€0.95m (n = 6). With the receipt of $45m from AbbVie, GLPG updated the 2018 guidance for cash burn of €140-160m (prev. €180-200m). **While many investors had already taken the value of the CF portfolio out of models following the PELICAN trial, we believe there was some concern GLPG would obtain full rights from AbbVie leading to significant R&D spend on a potentially uncompetitive programme. Therefore we see the restructuring of the agreement as a positive and believe the shares could be up c.2-3% this morning as the CF overhang is removed**.

- **CF collaboration with AbbVie restructured – GLPG to receive $45m upfront with no further R&D commitment to the programme**. GLPG and partner AbbVie announced that they have restructured their agreement, with AbbVie obtaining exclusive worldwide rights to all CF assets in the collaboration, thus bearing all costs going forward. GLPG will receive an upfront payment of $45m, potential milestones of up to $200m and tiered royalties on net sales (single digit to low teens in CF and single digits if the assets are used outside of CF). GLPG retain rights to GLPG2737 (C2 corrector) for use in indications outside of CF – it is not yet clear which indications GLPG will investigate this asset in. Given the fairly underwhelming results from FALCON part 1 (discussed below) and with Vertex and Proteostasis moving further ahead we see this as a positive for GLPG, as the overhang of CF is removed and R&D funds can be reallocated towards GLPG's innovative proprietary pipeline assets.

- **FALCON part 1 safety data tolerable, but efficacy data underwhelming – in line with the result from the PELICAN trial**: Part 1 of the Phase II FALCON trial tested 10 F508del H/H patients on GLPG's proprietary dual and triple combinations. The doublet combination only demonstrated a ppFEV1 improvement of c.3% and a mean decrease from baseline in sweat chloride concentrations of c.25mmol/L. The addition of the third agent, GLPG2737 (C2 corrector) did not impact CFTR activity. This compares to differences (non-placebo adjusted) of c.10-11% and 40-42mmol/L seen when Vertex have added either VX-659 or VX-445 to their approved CF doublet therapy Symdeco (tezacaftor/ivacaftor). VX-659 and VX-445 are the correctors that have been moved into Phase III trials by Vertex and thus represent efficacy the barrier for the FALCON study (see Table 1). Given the

underwhelming results from the Phase II PELICAN trial, our expectations for the FALCON trial were already low, and so we included no value for the CF portfolio in our model.

Table 1: Phase II FALCON data (part 1) vs. Phase II PELICAN data and Vertex triple combo regimens

Company	Galapagos				Vertex			
Potentiator	GLPG2451		Lumacaftor		Tezacaftor		Tezacaftor	
Corrector(s)	GLPG2222	GLPG2222 + GLPG2737	Ivacaftor + GLPG2737	Ivacaftor + Placebo	Ivacaftor + VX-659	Ivacaftor + Placebo	Ivacaftor + VX-445	Ivacaftor + Placebo
Patients	F508del H/H		F508del H/H		F508del H/H		F508del H/H	
Source	2W FALCON	4W FALCON	4W PELICAN		29 Days		29 Days	
Trial No.	NCT03540524		NCT03474042		NCT03224351		NCT03227471	
Phase	II		II		II		II	
n	10		14	8	-	-	-	-
Dose	ND	ND	GLPG2737 + ivacaftor (400mg/q12h) + ivacaftor (250mg/q12h)	Triple Placebo	VX-659 (400mg/qd) + tezacaftor (100mg/qd) + ivacaftor (150mg/q12h)	Triple Placebo	VX-445 (200mg/qd) + tezacaftor (100mg/qd) + ivacaftor (150mg/q12h)	Triple Placebo
Efficacy data (mean absolute CFB)								
ppFEV1 (%)	3		NR	NR	9.7	0.0	11.0	0.4
Placebo-adjusted			3.4		9.7		10.6	
p-value		no additional enhancement of CFTR activity	*0.08*		-		-	
Sweat chloride (mmol/L)	-25		NR	NR	-42.2	3.0	-39.6	0.8
Placebo-adjusted			-19.6		-45.2		-40.4	
p-value			*0.02*		-		-	

Orkambi (lumacaftor/ivacaftor) is packaged as lumacaftor 200mg/ivacaftor 125mg fixed dose combination tablets. Two tablets taken orally every 12 hours;
Symdeko (tezacaftor/ivacaftor) is co-packaged as tezacaftor 100mg/ivacaftor 150mg fixed dose combination tablets and ivacaftor 150mg tablets. One tablet (tezacaftor 100mg/ivacaftor 150mg) taken in the morning and one tablet (ivacaftor 150mg) taken in the evening, c. 12 hours apart
Source: Company data

- **€2018 cash burn guidance updated to reflect the $45m upfront CF payment from AbbVie:** GLPG updated their guidance for cash burn of €140-160m (prev. cash burn of €180-200m), which reflects the receipt of the $45m upfront payment received from AbbVie as part of the restructuring of the AbbVie CF collaboration.

- **€3Q'18 total revenues and other income beat BBG Consensus by 92% / €49.3m and Operating Profit beat BBG Consensus by €59m, benefitting from the €47.5m upfront payment from Novartis:** GLPG reported total revenues and other income of €103.2m, which was 92% ahead of BBG Consensus (€53.9m). We believe the majority of this beat was because GLPG recognised the full €47.5m upfront from Novartis for the rights to MOR106 whereas Cons. (and JPMe) spread this payment over c.2 years. Q3'1 Operating Profit was €12.3m vs. BBG Consensus of -€46.5m, again the beat largely due to the full recognition of the NOVN payment. This dropped down to the basic EPS of €0.29 vs. BBG Consensus of -0.95 (JPMe -0.81) (see Table 2 below).

Table 2: Galapagos 3Q'18 results (€m, except per share data)

	3Q'18A	Cons. 3Q'18E	% Diff	Abs. Diff (€m)	JPMe 3Q'18E	% Diff	Abs. Diff (€m)	3Q'17A	Y-o-Y Growth %
Revenues	94.9				45.0	111%	49.8	26.9	252%
Other income	8.3				7.4	13%	1.0	6.4	31%
Total revenues and other income	**103.2**	**53.9**	**92%**	**49.3**	**52.4**	**97%**	**50.8**	**33.3**	210%
R&D expenditure	80.3				87.3	-8%	(7.0)	56.3	43%
G&A expenses	9.7				7.5	29%	2.2	5.9	66%
S&M expenses	0.9				2.1	-58%	(1.2)	0.8	11%
Total operating expenses	**90.9**	**100.3**	**-9%**	**(9.4)**	**97.0**	**-6%**	**(6.0)**	**63.0**	44%
Operating Profit/(Loss)	**12.3**	**(46.5)**	**nm**	**58.8**	**(44.6)**	**nm**	**56.8**	**(29.7)**	**nm**

Net financial income/(expenses)	**2.1**	**(6.4)**	**nm**	**8.5**	**2.8**	**nm**	**(0.7)**	**(6.9)**	nm
Profit/(Loss) Before Tax	**14.4**	**(52.9)**	**nm**	**67.2**	**(41.8)**	**nm**	**56.1**	**(36.5)**	**nm**
Income taxes	0.5	0.0	-	0.5	0.0	-	0.5	(0.1)	nm
Tax Rate	*3.3%*	*nm*	-		*nm*	-		*nm*	-
Net Profit/(Loss)	**14.8**	**(52.9)**	**nm**	**67.7**	**(41.8)**	**nm**	**56.6**	**(36.6)**	**nm**
Basic income/(loss) per share	0.29	(0.95)	nm	1.24	(0.81)	nm	1.10	(0.73)	nm
Diluted incom/(loss) per share	0.28	(0.95)	nm	1.23	(0.81)	nm	1.09	(0.73)	nm

Source: Company data, BBRG Consensus, J.P. Morgan estimates

- **Conference call and R&D event webcast at 3:15pm BST (4:15pm CEST; 10:15am EDT)**: Dial in: +44 330 336 9127 (UK), +1 929 477 0402 (US), +31 20 703 8211 (Netherlands), +33 1 76 77 22 88 (France), +32 2 404 0659 (Belgium), CODE: 2357358. The webcast presentation can be accessed via GLPG's website http://www.glpg.com.

- **Next Catalysts**: The next key catalyst is topline read outs from the FINCH 1 & 3 trials in early 2019, which we believe have a good chance of being successful given the strong results see for filgotinib so far in the Phase II DARWIN programme and from the Phase III FINCH 2 trial.

European Healthcare (Pharma, Biotech)

James P Quigley [AC]
(44-20) 7742-1444
james.quigley@jpmorgan.com
Bloomberg JPMA QUIGLEY <GO>

James D Gordon
(44-20) 7742-6654
james.d.gordon@jpmorgan.com

Richard Vosser
(44-20) 7742-6652
richard.vosser@jpmorgan.com

Sarita Kapila (M.D.)
(44-20) 7134-4189
sarita.kapila@jpmchase.com

Laerke L Engkilde
(44-20) 7742-2917
laerke.engkilde@jpmorgan.com
J.P. Morgan Securities plc