Zacks Small-Cap Research
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Motif Bio Plc

(MTFB-NASDAQ)

MTFB: FDA Issues CRL for Iclaprim…

Based on our probability adjusted DCF model that takes into account potential future revenues from Iclaprim, MTFB is valued at $7 per share. This model is highly dependent upon continued clinical and commercial success of Iclaprim and will be adjusted accordingly based upon future clinical results and the company's execution.

Current Price (02/20/19)	$2.20
Valuation	**$7.00**

OUTLOOK

On Feb. 14, 2019, Motif Bio Plc (MTFB) announced that the U.S. FDA issued a complete response letter (CRL) in response to the company's new drug application (NDA) for iclaprim for the treatment of acute bacterial skin and skin structure infections (ABSSSI). The CRL stated that the FDA was not able to approve the drug at this time due to additional data needed regarding the potential for iclaprim to cause liver toxicity.

Motif will request a Type A meeting with the FDA very soon, and those meetings are typically granted 30-45 days following the request. At this meeting the company hopes to learn additional information regarding what additional data the FDA may need, although we don't believe additional clinical trials will be necessary as there was no indication of a problem with the clinical efficacy of the drug. We anticipate an update from the company following receipt of the official meeting minutes, which is usually 30 days following the meeting.

SUMMARY DATA

52-Week High	**$11.20**
52-Week Low	**$2.20**
One-Year Return (%)	**-77.39**
Beta	**1.79**
Average Daily Volume (sh)	**345,699**
Shares Outstanding (mil)	**15**
Market Capitalization ($mil)	**$33**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**7**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**

Risk Level	**Above Avg.**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2018	0.0 A	0.0 A	0.0 E	0.0 E	0.0 E
2019					0.0 E
2020					11.0 E

Earnings per ADS

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$1.50 A	-$1.50 A	-$1.07 A	-$1.07 A	-$3.87 A
2018	-$0.29 A	-$0.28 A	-$0.58 E	-$0.59 E	-$1.77 E
2019					-$1.40 E
2020					-$1.44 E

WHAT'S NEW

Business Update

CRL for Iclaprim

On February 14, 2019, Motif Bio Plc (MTFB) announced that the U.S. FDA issued a complete response letter (CRL) for the new drug application (NDA) for the company's lead asset iclaprim for the treatment of acute bacterial skin and skin structure infections (ABSSSI). The CRL stated that the FDA is unable to approve iclaprim at this point and that additional data would be required to determine the potential for liver toxicity. The CRL made no mention of any issues regarding the clinical efficacy of the drug.

We are surprised by the CRL, particularly since the FDA is citing the potential for liver toxicity as the reason for not approving the drug. It's also strange there wasn't an Advisory Committee meeting to discuss the potential for liver toxicity if the agency was concerned about it. The company has published extensively on the Phase 3 program for iclaprim, which included two randomized, double blind clinical trials (REVIVE-1 and REVIVE-2) where iclaprim was compared to vancomycin in patients with ABSSSI. The following tables show the incidence of increased alanine aminotransferase (ALT) and aspartate aminotransferase (AST) for each of the trials, with similar incidences for patients administered iclaprim and vancomycin. In addition, there was no incidence of increased bilirubin or other liver damage, thus we are unsure of why the FDA is concerned about potential liver toxicity.

REVIVE-1

Category	Iclaprim (N=293)	Vancomycin (N=297)
Increased ALT*	6 (2.0%)	5 (1.7%)
Increased AST*	6 (2.0%)	1 (4.3%)

Adapted from: Huang et al., 2018

REVIVE-2

	Iclaprim (n = 299)	Vancomycin (n = 302)
Increased AST concn[c]	6 (2.0)	5 (1.7)
Increased ALT concn[c]	5 (1.7)	7 (2.3)

[c]Investigator reported.

Adapted from: Holland et al., 2018

The company is planning to request a Type A meeting with the FDA very soon, and those meetings are typically granted 30-45 days after the request. Following the meeting, the company will receive the official meeting minutes approximately 30 days later, at which time we anticipate an update from the company. We don't believe that any additional clinical trials will be required, however we will be unsure of a timeline regarding resubmission of the NDA until after the company's meeting with the FDA.

Financial Update

On February 18, 2019, Motif announced that it entered into an amendment agreement with Hercules Capital, Inc. (HTGC) regarding the loan agreement entered into in November 2017. Motif had previously drawn down $15 million, and as part of the amended agreement Motif will make an immediate payment of $7 million with a further repayment of $0.5 million within the next 90 days or upon receipt of funds from an equity raise in excess of $2 million, whichever comes first. There will be a three-month interest only period on the remainder of the borrowed funds and there is no prepayment penalty. Following the $7 million payment to Hercules, Motif will have approximately $3 million in cash and cash equivalents and $7.7 million of outstanding debt, thus the company will need to raise additional capital soon.

Conclusion

The unexpected CRL for iclaprim is clearly a setback for Motif, however we are hopeful the company will be able to better understand the FDA's concerns and get clarity regarding what additional information will be necessary in order to refile the NDA. We anticipate an update in the next couple of months following the Type A meeting with the FDA. Reducing the debt load was a smart move, particularly as the company looks to raise additional capital in the near future. With the uncertainty surrounding the approval of iclaprim and the necessity to raise additional capital following the significant decrease in the share price we have made significant changes to our model that has resulted in lowering our valuation to $7 per share, although this valuation is highly fluid and ultimately will be dictated by the outcome of the FDA meeting.

PROJECTED FINANCIALS

Motif Bio Plc
Income Statement

Motif Bio Plc	2017 A	1H18 A	2H18 E	2018 E	2019 E	2020 E
Iclaprim (ABSSSI)	$0	$0	$0	$0	$0	$11
YOY Growth		-	-			
Iclaprim (HABP)	$0	$0	$0	$0	$0	$0
YOY Growth		-	-			
Iclaprim (CF)	$0	$0	$0	$0	$0	$0
YOY Growth		-	-			
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0
YOY Growth		-	-			
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$11**
YOY Growth		-	-			
Cost of Sales	$0	$0	$0	$0	$0	$2
Product Gross Margin		-	-			
Research & Development	$29.5	$6.9	$8.0	$14.9	$10.0	$17.0
General & Administrative	$8.5	$4.1	$8.0	$12.1	$15.0	$25.0
Other Expenses	$0	$0	$0	$0	$0	$0
Operating Income	($38.02)	($11.0)	($16.0)	($27.0)	($25.0)	($33.0)
Operating Margin		-	-			
Non-Operating Expenses (Net)	($6.8)	$3.2	($1.5)	$1.7	($3.0)	($3.0)
Pre-Tax Income	($44.8)	($7.8)	($17.5)	($25.3)	($28.0)	($36.0)
Income Taxes Paid	$0	($0)	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($44.8)**	**($7.8)**	**($17.5)**	**($25.3)**	**($28.0)**	**($36.0)**
Net Margin		-	-			
Net Loss per Share	**($0.19)**	**($0.03)**	**($0.06)**	**($0.09)**	**($0.07)**	**($0.07)**
Net Loss per ADS	**($3.87)**	**($0.57)**	**($1.17)**	**($1.77)**	**($1.40)**	**($1.44)**
YOY Growth		-	-			
Basic Shares Outstanding	231.5	272.2	300.0	286.1	400.0	500.0
ADS Oustanding	11.6	13.6	15.0	14.3	20.0	25.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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