Motif Bio PLC

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Motif closes in on approvals, potentially looking for partnership opportunities

In the world of US drug approvals, a positive result in a Phase 3 drug trial is generally celebrated with flourish: it might feel like you are nearing the end of the track. The finish line is near. One might think you're in the clear.

But it's not quite that simple.

WATCH: Motif Bio evaluating commercialisation options as decision time approaches
As Graham Lumsden, chief executive of **Motif Bio Plc** (LON:MTFB, NASDAQ:MTFB) knows all too well, getting a drug to market is no small task. The company is focused on a best-in-class drug, iclaprim, that targets bacteria resistant to most other commonly used antibiotics.

"Were spending a lot of time thinking about how we come to market in the US…" said Lumsden. "We're having some very constructive conversations with some potential partners."

A potential partnership could be beneficial for Motif, from an efficiency and capital standpoint.

Major milestones achieved, more to come
Motif faces more work in the coming months as it continues to push towards final approval.

It passed a major milestone last year when it concluded a second phase III clinical trial on iclaprim and initiated a rolling submission to the US Food and Drug Administration, while also preparing a marketing authorization application to the European Medicines Agency. The submission is expected to be completed in the second quarter of 2018.

Potential partnerships
One question looming on Lumsden's mind is figuring out the best way to come to market in the US. Should Motif go at it alone, or alongside a partner?

Lumsden says there are many paths Motif could go down: from a co-promotion effort, a licensing deal, or even a full M&A transaction.

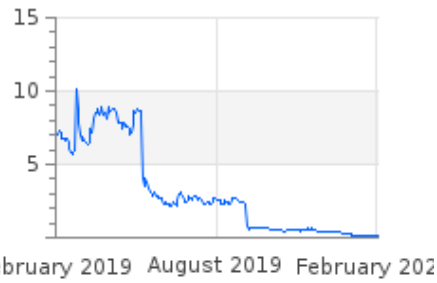
"It's our preferred path to try to find a partner for the US market," said Lumsden. "If we have to do it ourselves, we can, we will, we just don't think it's the optimal way to do it."

Lumsden stresses that in these types of situations, it can be far more effective and efficient to partner up. Potentially, that could be with another company that also has a single asset, perhaps in this case, a gram-negative antibiotic, which could complement nicely with iclaprim, which is a gram-positive antibiotic. However, all options are still on the table.

"We're anticipating a decision, hopefully an approval from the FDA, in the first quarter [2019]," said Lumsden.

Price:	0.132
Market Cap:	£640.66 k

1 Year Share Price Graph



Share Information

Code:		MTFB
Listing:		AIM
52 week	**High**	**Low**
	14.5	**0.1063**
Sector:		**Pharma & Biotech**
Website:		**www.motifbio.com**

Company Synopsis:
Motif Bio is a clinical-stage biopharmaceutical company focused on developing novel antibiotics designed to be effective against serious and life-threatening infections caused by multi-drug resistant Gram-positive bacteria, including MRSA.

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Medical science liaisons to play important role
About about six months ahead of the potential approval, there will likely be a push to increase awareness of iclaprim in both the medical community and hospital formulary committees. Generally, this is done by a team of medical science liaisons (MSLs), who use the scientific literature as an educational tool. In the case of Motif, it may make sense to team up with another partner, when it comes to forming the MSL team. Most people expect a decision on this to be made by the third quarter.

Beneficial for those with impaired kidneys
Iclaprim is a gram-positive antibiotic targeted especially to those who may have impaired kidneys, and/or face other compromising factors, such as diabetes. It is estimated that up to 26% of the 3.6mln patients hospitalized annually with acute bacterial skin and skin structure infections have kidney disease.

READ: Home plate beckons for Motif Bio
Antibiotics are the most commonly prescribed class of drug, representing a global market of $40bln. New, innovative approaches are needed, due to ever-evolving drug-resistant strains of bacteria.

The numbers:
Motif just released their financial results for the year, which showed the company spent US$29.5mln on research and development -- a reflection of the work it has completed in clinical trials ahead of the regulatory application for iclaprim. Upon approval, iclaprim will be eligible for 10 years of market exclusivity in the US, starting from the date of first approval.

From a cash perspective, the figure was substantially down year-over-year, reflecting the high cost of getting a drug to market, which was US$34.8mln, and more importantly, Motif was sitting on US$22.7mln of cash at the year-end with access to US$20mln of debt financing.

Global and US opportunity looks bright
The global market for antibiotic drugs targeting difficult-to-treat infections, such as iclaprim, is an estimated US$3.0bln and is dominated by vancomycin, a traditional first-line treatment.

From an approval perspective, the future looks bright, compared to a stagnant few decades. From 2003 to 2010, only one new antibiotic was approved by the US Food and Drug Administration (FDA), and 10 since 2010. However, this year the FDA could approve as many as half a dozen new drugs, all from small players, such as Motif.

READ: Motif Bio to present new Iclaprim safety and efficacy data at top European conference
This weekend, Motif will present data at the 28th European Congress of Clinical Microbiology and Infectious Diseases which shows iclaprim still works on a variety of antibiotic-resistant pathogens such as methicillin-resistant (MRSA) and methicillin-susceptible (MSSA) Staphylococcus aureus.

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