Motif Bio Reports Fiscal Year 2018 Results

April 15, 2019

NEW YORK, April 15, 2019 (GLOBE NEWSWIRE) -- Motif Bio plc (AIM/NASDAQ: MTFB), a clinical-stage biopharmaceutical company specialising in developing novel antibiotics, today announced financial results for the year ended December 31, 2018.

Dr. Graham Lumsden, Chief Executive Officer, said: “Motif Bio had an incredibly productive year in 2018, including submitting a New Drug Application to the U.S. FDA for iclaprim for the treatment of patients with acute bacterial skin and skin structure infections. Unfortunately, in February 2019 we unexpectedly received a Complete Response Letter from FDA notifying Motif that the NDA for iclaprim could not be approved as submitted. The Agency has asked for additional data to assess the potential for liver toxicity and we have a confirmed FDA meeting date of May 3, 2019 to discuss the concerns noted in the Complete Response Letter. We expect to be joined at the meeting by two external experts and anticipate a collaborative discussion and hopefully an acceptable path forward. We believe that iclaprim can be a valuable option for patients and their providers who are in need of new antibiotic treatment options.”

Corporate and Development Highlights

- New Drug Application (NDA) submitted to and accepted for priority review by U.S. Food & Drug Administration (FDA) for iclaprim for treatment of patients with acute bacterial skin and skin structure infections (ABSSSI).
- Notice of Allowance from the United States Patent and Trademark Office for two patent applications. The claims relate to the use of iclaprim to treat patients with bacterial infections, including but not limited to ABSSSI, hospital-acquired bacterial pneumonia and *Staphylococcus aureus* lung infections in patients with cystic fibrosis. The two method of use patents, which have now issued, will expire in November 2037.
- Results from the Phase III REVIVE-2 trial and pooled efficacy and safety results from the REVIVE-1 and -2 Phase III trials in ABSSSI published in peer-reviewed medical journals.
- Data on iclaprim safety and efficacy and potential cost avoidance data presented at major medical conferences.
- Jonathan Gold appointed interim Chief Financial Officer in February 2018; Stephanie Noviello, MD, MPH joins as Vice President, Clinical Development in May 2018.

Full Year 2018 Financial Results Highlights

- Motif Bio reported a net loss of $14.0 million or $(.05) per share, basic and $(.07) per share, diluted for 2018, compared to $44.8 million, or $(0.19) per share, basic and diluted for 2017.
- Research and development expenses decreased to $11.0 million for 2018, compared to $29.5 million for 2017. This decrease was primarily attributable to a $22.1 million reduction in expense for the iclaprim Phase III clinical trial program, which was completed in 2017. This decrease was partially offset by a $3.6 million increase in costs relating to regulatory and clinical operating activities, chemistry manufacturing and control requirements and other non-clinical development activities.
- General and administrative expenses were $7.6 million for 2018, compared to $8.5 million in 2017. This decrease was primarily attributable to a $0.4 million reduction in stock-based compensation, which was higher in the 2017 period partially due to a previously disclosed out-of-period correction and a $1.3 million reduction in legal, investor relations and other professional fees. This decrease was partially offset by a $0.7 million increase in employee cash compensation.
- Raised $12.7 million of net proceeds through the issuance of ordinary shares London’s AIM market.
- Cash and cash equivalents of approximately $12.3 million as of December 31, 2018.
- 296.7 million ordinary shares outstanding as of December 31, 2018.

Post Period End Highlights

- Received Complete Response Letter (CRL) from FDA regarding NDA for iclaprim; Motif’s request to meet with the FDA to discuss the points raised in the CRL was granted and a meeting is scheduled for May 3, 2019.

- Bruce Williams appointed interim Chairman following resignation of Richard Morgan from Board of Directors.
- Raised $3.3 million of net proceeds through the issuance of ordinary shares London's AIM market.
- 342.5 million ordinary shares outstanding as of April 11, 2019.

Motif Bio will file later today its U.S. Annual Report on Form 20-F for the year ended December 31, 2018 with the U.S. Securities and Exchange Commission (SEC). The Form 20-F will be available to download, either from the Investors section of the Company website www.motifbio.com or the SEC website at www.sec.gov. An electronic version of the UK Annual Report and Accounts will be made available on Motif Bio's website under "AIM Investors" in due course and announced when available.

Motif Bio expects to hold its next Annual General meeting at 1 PM BST on May 22, 2019 at the offices of DLA Piper UK LLP at 160 Aldersgate Street London EC1A 4HT, United Kingdom.

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Note to Editors

Motif Bio plc (AIM/NASDAQ: MTFB) 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. The Company's lead product candidate is iclaprim. Motif Bio is seeking approval of iclaprim from the U.S. Food & Drug Administration (FDA) for the treatment of acute bacterial skin and skin structure infections (ABSSSI). More than 3.6 million patients with ABSSSI are hospitalised annually in the U.S. It is estimated that up to 26% of hospitalized ABSSSI patients have renal impairment.

The Company also has plans to develop iclaprim for hospital acquired bacterial pneumonia (HABP), including ventilator associated bacterial pneumonia (VABP), as there is a high unmet need for new therapies in this indication. A Phase 2 trial in patients with HABP has been successfully completed and a Phase 3 trial is being planned. Additionally, iclaprim has been granted orphan drug designation by the FDA for the treatment of *Staphylococcus aureus* lung infections in patients with cystic fibrosis and is in preclinical development for this indication.

Iclaprim has received Qualified Infectious Disease Product (QIDP) designation from the FDA together with Fast Track status for the ABSSSI indication. If approved for the ABSSSI indication as a New Chemical Entity, iclaprim will be eligible for 10 years of market exclusivity in the U.S. from the date of first approval, under the Generating Antibiotic Incentives Now Act (the GAIN Act). In Europe, 10 years of market exclusivity is anticipated. Motif is also building a patent estate to provide additional protection for iclaprim and has two U.S. method of use patents issued that will expire in 2037.

Forward-Looking Statements

This release contains forward-looking statements. Words such as "expect," "believe," "intend," "plan," "continue," "may," "will," "anticipate," and similar expressions are intended to identify forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause Motif Bio's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Motif Bio believes that these factors include, but are not limited to, (i) the timing, progress and the results of clinical trials for Motif Bio's product candidates, (ii) the timing, scope or likelihood of regulatory filings and approvals for Motif Bio's product candidates, (iii) Motif Bio's ability to successfully commercialise its product candidates, (iv) Motif Bio's ability to effectively market any product candidates that receive regulatory approval, (v) Motif Bio's commercialisation, marketing and manufacturing capabilities and strategy, (vi) Motif Bio's expectation regarding the safety and efficacy of its product candidates, (vii) the potential clinical utility and benefits of Motif Bio's product candidates, (viii) Motif Bio's ability to advance its product candidates through various stages of development, especially through pivotal safety and efficacy trials, (ix) Motif Bio's estimates regarding the potential market opportunity for its product candidates, (x) Motif Bio's ability to raise additional capital to sustain its operations and pursue its strategy and (xi) the factors discussed in the section entitled "Risk Factors" in Motif Bio's Annual Report on Form 20-F filed with the SEC on April 15, 2019, which is available on the SEC's web site, www.sec.gov. Motif Bio undertakes no obligation to update or revise any forward-looking statements.

Motif Bio plc
Consolidated statements of comprehensive loss
For the years ended December 31, 2018, 2017 and 2016
(in thousands, except share and per share data)

	Year ended December 31, 2018 US $	Year ended December 31, 2017 US $	Year ended December 31, 2016 US $
Continuing operations			
General and administrative expenses	(7,635)	(8,542)	(4,912)
Research and development expenses	(10,988)	(29,475)	(34,795)
Gains on settlement of contract disputes	—	—	83
Operating loss	(18,623)	(38,017)	(39,624)
Interest income	113	134	70
Interest expense	(2,160)	(275)	(383)
Net foreign exchange gains (losses)	40	(238)	(251)
Gain (loss) from revaluation of derivative liabilities	6,654	(6,392)	(136)
Loss before income taxes	(13,976)	(44,788)	(40,324)
Income tax expense	(9)	(22)	—
Net loss for the year	(13,985)	(44,810)	(40,324)
Total comprehensive loss for the year	(13,985)	(44,810)	(40,324)
Net loss per share			
Basic	(0.05)	(0.19)	(0.35)
Diluted	(0.07)	(0.19)	(0.35)
Weighted average number of ordinary shares			
Basic	284,530,534	231,530,091	116,558,191
Diluted	287,131,688	231,530,091	116,558,191

Motif Bio plc
Consolidated statements of financial position
As at December 31, 2018 and 2017

(in thousands)	December 31, 2018 US $	December 31, 2017 US $
ASSETS		
Non-current assets		
Intangible assets	6,196	6,196
Other non-current assets	18	23
Total non-current assets	6,214	6,219
Current assets		
Prepaid expenses and other receivables	231	318
Cash and cash equivalents	12,279	22,651
Total current assets	12,510	22,969
Total assets	18,724	29,188

LIABILITIES				
Non-current liabilities				
Term loan, net of current portion	10,131		14,057	
Other non-current liabilities	196		23	
Total non-current liabilities	10,327		14,080	
Current liabilities				
Trade payables and accrued liabilities	7,207		10,890	
Term loan, current portion	4,327		—	
Payable on completion of clinical trial	—		500	
Derivative liabilities	5,789		12,626	
Total current liabilities	17,323		24,016	
Total liabilities	27,650		38,096	
Net assets (liabilities)	(8,926	)	(8,908	)
EQUITY				
Share capital	4,032		3,589	
Share premium	93,456		80,873	
Group reorganization reserve	9,938		9,938	
Accumulated deficit	(116,352	)	(103,308	)
Total deficit	(8,926	)	(8,908	)