
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934**

For the Month of: August 2018

Commission File Number: 001-37847

MOTIF BIO PLC
(Translation of registrant's name into English)

**125 Park Avenue
25th Floor
New York , New York 10017**
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

MOTIF BIO PLC
FORM 6-K

MOTIF BIO ANNOUNCES FDA ACCEPTANCE OF NEW DRUG APPLICATION WITH PRIORITY REVIEW FOR ICLAPRIM FOR TREATMENT OF ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS

On August 14, 2018, Motif Bio plc (the “Company”) issued a press release, a copy of which is attached as Exhibit 99.1 to this report on Form 6-K, to announce that the U.S. Food & Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for iclaprim, a targeted, Gram-positive investigational antibiotic, for the treatment of acute bacterial skin and skin structure infections (ABSSSI). This means that the FDA has determined that the application is sufficiently complete to perform a substantive review. The NDA has been granted Priority Review, and the FDA has set a target decision date under the Prescription Drug User Fee Act (PDUFA) of February 13, 2019.

The information contained in this report on Form 6-K, excluding the press release attached as Exhibit 99.1, is hereby incorporated by reference into the Company’s Registration Statements on Form F-3 (File Nos. 333-222614 and 333-222042), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibits

Press release issued by Motif Bio plc, dated August 14, 2018, entitled “Motif Bio Announces FDA Acceptance of New Drug Application with [Exhibit 99.1](#) Priority Review for Iclaprim for Treatment of Acute Bacterial Skin and Skin Structure Infections.”

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MOTIF BIO PLC

Date: August 14, 2018

By: /s/ Graham Lumsden
Name: Graham Lumsden
Title: Chief Executive Officer

Motif Bio Announces FDA Acceptance of New Drug Application with Priority Review for Iclaprim for Treatment of Acute Bacterial Skin and Skin Structure Infections

PDUFA action date set for February 13, 2019

NEW YORK, Aug. 14, 2018 (GLOBE NEWSWIRE) -- Motif Bio plc (AIM/NASDAQ: MTFB), a clinical-stage biopharmaceutical company specialising in developing novel antibiotics, today announced that the U.S. Food & Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for iclaprim, a targeted, Gram-positive investigational antibiotic, for the treatment of acute bacterial skin and skin structure infections (ABSSSI). This means that the FDA has determined that the application is sufficiently complete to perform a substantive review. The NDA has been granted Priority Review, and the FDA has set a target decision date under the Prescription Drug User Fee Act (PDUFA) of February 13, 2019.

"The NDA acceptance by the FDA is an important milestone for Motif Bio and reflects the dedication and commitment of our team who have worked tirelessly to accomplish this," said Graham Lumsden, Chief Executive Officer of Motif Bio. "We believe that, if approved, iclaprim could be an important new treatment option for patients with serious skin infections. We look forward to working closely with the FDA as we move through the review process with the goal of bringing iclaprim to patients as quickly as possible."

More than 3.6 million patients with ABSSSI are hospitalised annually in the U.S. It is estimated that up to 26% of hospitalised ABSSSI patients have renal impairment. Hospitalised patients with obesity, diabetes and/or poor kidney function are particularly vulnerable to vancomycin-associated kidney injury. Many standard of care Gram-positive antibiotics are not suitable for treatment of hospitalised ABSSSI patients with these conditions due to efficacy and/or safety issues.

The NDA includes data from two Phase 3 trials (REVIVE-1 and REVIVE-2) evaluating iclaprim for the treatment of patients with ABSSSI. In both trials, iclaprim achieved the primary endpoint of non-inferiority (NI) (10% margin) compared to vancomycin, the current standard of care, at the early time point (ETP), 48 to 72 hours after the start of administration of the study drug, in the intent-to-treat (ITT) patient population. Iclaprim also achieved NI (10% margin) at the test of cure endpoint, 7 to 14 days after study drug discontinuation, in the ITT patient population.

Iclaprim has received Qualified Infectious Disease Product (QIDP) designation from the FDA. If iclaprim is approved as a new chemical entity with QIDP designation, it will be eligible for 10 years of market exclusivity in the U.S. starting from the date of approval, under the Generating Antibiotic Incentives Now Act (the GAIN Act).

For further information please contact:

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Note to Editors:

About Iclaprim

Iclaprim is a novel investigational antibiotic with a targeted Gram-positive spectrum of activity. In contrast to commonly used broad-spectrum antibiotics, this “precision medicine approach” is consistent with antibiotic stewardship principles which, among other things, seek to reduce the inappropriate use of broad-spectrum products to avoid the build-up of resistance and to lessen the impact on the microbiome of the patient.

Iclaprim has a different and underutilised mechanism of action compared to most other antibiotics. Following positive results from two Phase 3 trials (REVIVE-1 and REVIVE-2), a New Drug Application (NDA) has been submitted to the U.S. Food & Drug Administration (FDA) for the treatment of acute bacterial skin and skin structure infections (ABSSSI). To date, iclaprim has been studied in over 1,400 patients and healthy volunteers. Clinical and microbiological data indicate that iclaprim has a targeted Gram-positive spectrum of activity, low propensity for resistance development and favourable tolerability profile. In clinical studies, iclaprim has been administered intravenously at a fixed dose with no dosage adjustment required in patients with renal impairment or in obese patients. The iclaprim fixed dose may, if approved, help reduce the resources required in hospitals since dosage adjustment by health care professionals is avoided and overall hospital treatment costs may be lower, especially in patients with renal impairment. Many standard of care Gram-positive antibiotics are not suitable for hospitalised ABSSSI patients with renal impairment due to efficacy and/or safety issues.

About Motif Bio

Motif Bio plc (AIM/NASDAQ: MTFB) is a clinical-stage biopharmaceutical company focused on developing novel antibiotics for hospitalised patients and 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. Following positive results from two Phase 3 trials (REVIVE-1 and REVIVE-2), a New Drug Application (NDA) has been submitted to 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 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. If approved 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.

Forward-Looking Statements

This press 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, and (x) 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 10, 2018, 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.