
**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: **September 2017**

Commission File Number: **001-37847**

MOTIF BIO PLC

(Exact name of registrant as specified in its charter)

125 Park Avenue

25th Floor

New York, New York 10011

(Address of principal executive offices)

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 ICLAPRIM GRANTED ORPHAN DRUG DESIGNATION BY US FDA FOR TREATMENT OF STAPHYLOCOCCUS AUREUS LUNG INFECTIONS IN PATIENTS WITH CYSTIC FIBROSIS

On September 15, 2017, Motif Bio plc issued a press release, a copy of which is attached as Exhibit 99.1 to this report on Form 6-K, announcing that the US Food and Drug Administration has granted its investigational drug candidate, iclaprim, Orphan Drug Designation for treatment of *Staphylococcus aureus* lung infections in patients with cystic fibrosis.

The information contained in Exhibit 99.1 is being furnished to the U.S. Securities and Exchange Commission (the “Commission”) and shall not be deemed incorporated by reference into any of the registrant’s registration statements or other filing with the Commission.

Exhibits

Exhibit 99.1 Press release issued by Motif Bio plc, dated September 15, 2017, entitled “Motif Bio announces iclaprim granted Orphan Drug Designation by US FDA for treatment of *Staphylococcus aureus* lung infections in patients with cystic fibrosis.”

SIGNATURES

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

MOTIF BIO PLC

By: /s/ Robert Dickey IV
Name: Robert Dickey IV
Title: Chief Financial Officer

Date: September 15, 2017



15 September 2017

Motif Bio plc
 (“Motif Bio” or the “Company”)

**Motif Bio announces iclaprim granted Orphan Drug Designation by US FDA
 for treatment of *Staphylococcus aureus* lung infections in patients with cystic fibrosis**

Motif Bio plc (AIM/NASDAQ: MTFB), a clinical stage biopharmaceutical company specialising in developing novel antibiotics, announced today that the US Food and Drug Administration (“FDA”) has granted its investigational drug candidate, iclaprim, Orphan Drug Designation for the treatment of *Staphylococcus aureus* lung infections in patients with cystic fibrosis.

Orphan designation grants special status to a drug or biologic under development to treat a rare disease or condition and qualifies the sponsor of the product for various development incentives, including tax credits for qualified clinical testing, waiver of user fees and potentially up to seven years of market exclusivity for the given indication, if approved.

“Staphylococcus aureus, including MRSA, is one of the common causes of lung infections in patients with cystic fibrosis and we do not believe that any antibiotic has been approved for this indication. Some 80% or more of patients with cystic fibrosis die as a result of respiratory infections caused by a variety of bacteria, and MRSA infections have been growing in recent years,” said Graham Lumsden, Chief Executive Officer of Motif Bio. *“Formulation development work is underway at Motif Bio to explore potential intravenous and inhaled formulations designed specifically for cystic fibrosis patients.”*

Iclaprim has been studied in an animal model of chronic pulmonary methicillin resistant *Staphylococcus aureus* (“MRSA”) infection, which mimics the pathophysiology observed in the lungs of patients with cystic fibrosis. These data will be presented at IDWeek on October 6, 2017 in San Diego, CA.

For further information please contact:

Motif Bio plc

Graham Lumsden (Chief Executive Officer)
 Robert Dickey IV (Chief Financial Officer)

info@motifbio.com

Peel Hunt LLP (NOMAD & BROKER)

Dr Christopher Golden
 Oliver Jackson

+ 44 (0)20 7418 8900

Northland Capital Partners Limited (BROKER)

Patrick Claridge/ David Hignell
 John Howes/ Rob Rees (Broking)

+44 (0)203 861 6625

Walbrook PR Ltd. (UK FINANCIAL PR & IR)

Paul McManus
 Mike Wort

+44 (0) 20 7933 8780 / motifbio@walbrookpr.com

Mob: +44 (0)7980 541 893

Mob: +44 (0)7900 608 002

MC Services AG (EUROPEAN IR)
Raimund Gabriel

+49 (0)89 210 2280
raimund.gabriel@mc-services.eu

The Trout Group (US IR)
Michael Gibralter

+1 (646) 378-2938
mgibralter@troutgroup.com

Lazar Partners (US PR)
Chantal Beaudry
Amy Wheeler

motiflp@lazarpartners.com
+1 (646) 871-8480
+1 (646) 871-8486

Notes to Editors

About Iclaprim

Iclaprim is a novel investigational antibiotic that has a different and underutilised mechanism of action compared to other antibiotics. Iclaprim exhibits potent *in vitro* activity against Gram-positive clinical isolates of many genera of staphylococci, including methicillin-resistant *Staphylococcus aureus* (MRSA). Iclaprim is rapidly bactericidal, achieving 99.9% *in vitro* kill against MRSA within 4 to 6 hours of drug exposure versus 8 to 10 hours for vancomycin. To date, iclaprim has been studied in over 1,300 patients and healthy volunteers. 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.

About Motif Bio

Motif Bio plc (AIM/NASDAQ: MTFB) is a clinical-stage biopharmaceutical company engaged in the research and development of novel antibiotics designed to be effective against serious and life-threatening infections in hospitalised patients caused by multi-drug resistant bacteria, including MRSA. The Company's lead product candidate, iclaprim, is being developed for high-risk MRSA patient populations. The first proposed indication, and near-term commercial opportunity, is for the treatment of acute bacterial skin and skin structure infections (ABSSSI), one of the most common bacterial infections, with 3.6 million patients hospitalised annually in the US. The Company believes that iclaprim may be suitable for first-line empiric therapy in ABSSSI patients, especially those with renal impairment, with or without diabetes. Unlike current standard of care antibiotics, in clinical trials to date, nephrotoxicity has not been observed with iclaprim and dosage adjustment has not been required in patients with renal impairment.

Iclaprim has an underutilised mechanism of action compared to other antibiotics. Clinical and microbiology data indicate iclaprim has a targeted Gram-positive spectrum of activity, low propensity for resistance development, fixed dose administration and favourable tolerability profile. Additionally, data support that the inactive metabolites of iclaprim clear through the kidneys. 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 was conducted to study iclaprim in patients with HABP. Iclaprim has been studied in an animal model of chronic pulmonary MRSA infection which mimics the pathophysiology observed in patients with cystic fibrosis. Results from this study will be presented at IDWeek on October 6, 2017 in San Diego, CA. Iclaprim has received Qualified Infectious Disease Product (QIDP) designation from the FDA together with Fast Track status. Upon acceptance by the

FDA of a New Drug Application (NDA), iclaprim will receive Priority Review status and, if approved as a New Chemical Entity, will be eligible for 10 years of market exclusivity in the US from the date of first approval, under the Generating Antibiotic Incentives Now Act (the GAIN Act). In Europe, 10 years of data 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 plc’s Annual Report on Form 20-F filed with the SEC on May 1, 2017, which is available on the SEC’s web site, www.sec.gov. Motif Bio plc undertakes no obligation to update or revise any forward-looking statements.