

## **Motif Bio Raises \$35 Million in AIM IPO**

### **Overview**

New York-based Motif Bio raised \$35 million in its recent IPO on the London Stock Exchange's AIM and commanded an opening market capitalization of \$86 million. The Company is pre-revenue and \$14 million has been invested since inception.

Motif Bio is a clinical stage biopharmaceutical company that specializes in developing novel antibiotics designed to be effective against serious and life-threatening infections caused by multidrug-resistant bacteria. The Company has been focused on drug discovery and development since 2009 and acquired its leading drug candidate, iclaprim, as a result of a merger with a Maryland-based company simultaneous with the IPO. Iclaprim is in Phase III, the final stage of clinical trials, with plans for commercialization in 2018.

Resistance to antibiotics is a major global health threat. So called 'superbugs' are developing resistance to currently available antibiotics faster than new, effective antibiotics are being developed. Each year these drug-resistant bacteria infect more than 2 million people across the U.S. and kill at least 23,000 according to the U.S. Centers for Disease Control and Prevention (CDC). In the past, some of the most dangerous superbugs were confined to healthcare settings, however, some strains are out in the community and even healthy people can become infected. One common superbug seen outside hospitals is methicillin-resistant *Staphylococcus aureus* (MRSA), which can cause skin infections and, in more serious cases, pneumonia or bloodstream infections. The CDC estimates that more than 80,000 aggressive MRSA infections and 11,000 related deaths occur each year in the U.S. Dr. Margaret Chan, Director-General of the World Health Organization said, "A post-antibiotic era means, in effect, an end to modern medicine as we know it. Things as common as strep throat or a child's scratched knee could once again kill. Some sophisticated interventions, like hip replacements, organ transplants, cancer chemotherapy and care of preterm infants would become far more difficult, or even too dangerous, to undertake". The worldwide antibacterial market was valued at \$44 billion in 2010.

Motif Bio is designing iclaprim to be administered in hospitals as an intravenous infusion. Hospital settings are where novel antibiotics effective against multidrug-resistant bacteria are most urgently needed since this is where patients often succumb to serious, life-threatening infections that require immediate treatment with the best available antibiotic. Commercialization of hospital products is relatively easy and can be done with fewer resources than in the broader community for the simple reason that there are fewer hospital healthcare professionals to communicate with, compared to having to educate a much larger number of primary care physicians and other practitioners.

The first indication the Company will be pursuing with iclaprim is Acute Bacterial Skin and Skin Structure Infections (ABSSSI), a common, serious, infectious disease involving multidrug-resistant bacteria. Within hospitalized patients in the U.S., skin and soft tissue infections have increased by 176% from 1997 to 2009. Iclaprim works differently than most other antibiotics and has a very low propensity for resistance development. This is important because as bacteria continue to develop resistance, several different classes of antibiotics, with different mechanisms of action (MOAs), will be needed to help fight the looming public health crisis. Iclaprim can even be used against bacteria that have developed resistance to trimethoprim, the only other commonly used antibiotic that shares iclaprim's MOA.

The U.S. Food and Drug Administration (FDA) has agreed to Motif Bio's Phase III clinical development program for iclaprim. The FDA confirmed that two ABSSSI trials meeting their pre-specified primary endpoints are required for marketing approval. The Company will be requesting the Qualified Infectious Disease Product (QIDP) designation from the FDA, which, as provided under the Generating Antibiotic Incentives Now Act (GAIN Act), would make iclaprim eligible for the FDA's Fast Track program and additional market exclusivity.

The FDA's Fast Track program provides priority review and allows for more frequent interactions with the FDA during clinical development. Companies can submit completed sections of their New Drug Applications (NDAs) on a rolling basis, expediting the FDA review process and, ultimately, marketing approval. The GAIN Act also extends market exclusivity from five years to 10 years from the date of approval of a NDA, which is an important financial incentive for companies developing new antibiotics since the course of treatment is typically of a short duration, days or weeks, compared to other drugs that may be administered for years or indeed a patient's lifetime. The two Phase III clinical trials will take 18 months to complete and, assuming positive results, iclaprim could be ready for commercialization 18 months later.

Although the original patents for iclaprim were abandoned by the Maryland-based company that merged with Motif Bio, if the Company is able to secure QIDP designation from the FDA, iclaprim will have 10 years of market exclusivity. In Europe, the generation of additional data in clinical trials can result in 10 years of data exclusivity (i.e. not allowing others to piggyback on Motif Bio's R&D efforts). As an additional barrier against competitors, the Company will build a global patent portfolio for iclaprim as clinical development progresses.

Motif Bio is essentially a 'virtual company'. The CEO is employed by the Company and is based in New York. The CFO is also based in New York and provided to the Company on a part-time basis under an agreement with the Strategic Investor. Motif Bio has one employee based in London who provides company secretarial services. The Company has seven Non-Executive Directors, a four-member Scientific Advisory Board and a dozen Scientific Consultants with expertise across medicinal chemistry, pharmacology, toxicology, drug development, regulatory issues, intellectual property and business development. In addition, the Company has engaged and will continue to work with a New Jersey-based firm that provides consultancy services by leveraging a network of biopharmaceutical R&D scientists. Finally, Motif Bio signed a letter-of-intent and interim agreements with a leading global Contract Research Organization (CRO). The CRO will be responsible for carrying out the two Phase III clinical trials of iclaprim. This CRO is one of the world's top five providers of clinical trial management, having contributed to the development of all of the top 50 prescription medicines currently on the market. They have unique insights into infectious disease clinical trials, having worked with over 17,000 patients in more than 150 studies.

### **Historic Financial Information**

Motif Bio has been focused on drug discovery and development since 2009, acquired its leading drug candidate, iclaprim, simultaneous with the IPO and is pre-revenue. As of June 30, 2015, the Company had \$3m of cash, \$6m of intangible assets, \$6m of liabilities and an accumulated deficit of \$14m.

### **Key Listing Metrics**

- \$34.76 million gross was raised, \$31.73 million net of offering costs, intended to be used to:
  - Complete preparations to enter two Phase III, randomized, double-blind, multicenter trials
    - Ensure that the trial sites are set up and ready for the trials to be conducted
    - Requalify the existing iclaprim active pharmaceutical ingredients
    - Formulate the clinical trial supplies for iclaprim
    - Source the clinical trial supplies for the competing drug, vancomycin
    - Prepare for patient enrollment
  - Conduct the two Phase III trials (an additional ca. \$25 million will have to be raised)
  - Advance and augment the Company's novel antibiotic programs
  - Start development work on oral formulations of iclaprim
  - Explore additional indications for iclaprim and related formulations
- Offering costs amounted to 8.72% of the gross capital raised
  - The offering was undertaken on a 'best efforts' basis, as opposed to being underwritten
    - Broking commission of 5%
    - Corporate finance fee of £250,000 (\$395,000)
    - Five-year warrant over 1% of the enlarged share capital struck at the IPO price
- Opening market capitalization of \$85.51 million
- Dilution to existing shareholders of 40.65%
- Free float of 37.9%

### **Shareholder Base**

The Company had 64.2 million shares outstanding prior to the IPO and issued 44.0 million new shares for cash in the IPO, leaving the Company with 108.2 million shares outstanding. The table below details those who held 3% or more of the Company prior to and after the IPO, along with other holdings that are of interest.

Shareholder	Pre-IPO %	Post-IPO %
Strategic Investor	44.09	26.17 <sup>1</sup>
Former CEO	7.49	4.44 <sup>2</sup>
Private Investor	7.49	4.44 <sup>2</sup>
Financial Spread Bettor	6.23	3.69
Directors	1.45	0.88 <sup>1</sup>
Other Historic Investors	33.25	19.73
Global Institution (Various Funds)	-	23.10
London-based Institution (Various Funds)	-	8.50
Edinburgh-based Institution (Various Funds)	-	4.25
Other New U.K. Investors	-	4.80
Totals	100.00	100.00

<sup>1</sup> Subject to a 12-month lock-in and customary orderly market provisions for a further 12 months.

<sup>2</sup> Subject to a 12-month lock-in.

As a result of the AIM IPO, the Company has raised approximately half of the amount that will be required to conduct the two Phase III trials. The new, U.K.-based, blue-chip institutional investors have broadened the shareholder base and provided a substantial amount of long-term capital, which should provide comfort to other investors to provide additional capital for the current and prospective drug development programs and/or facilitate the formation of strategic partnerships with pharmaceutical companies. The Company has adopted a Share Option Plan (Plan) so as to enhance its ability to attract, retain and incentivize high caliber employees. A Sub-Plan was also adopted for non-employees (i.e. directors and consultants) which will be governed by the same rules as the Plan.

### **Board of Directors and Corporate Governance**

The Board consists of two Executive Directors (the CEO and the CFO), a Non-Executive Chairman (NEC) and six independent Non-Executive Directors (NEDs); all with solid resumes and a good blend of complementary experiences and skill sets.

Companies listed on AIM are not required to comply with the U.K. Corporate Governance Code published by the Financial Reporting Council, which is mandatory for companies listed on the Main Market of the London Stock Exchange. AIM-listed companies typically comply with, and the Company intends, in so far as is practicable given its size, board structure, stage-of-development and resources, the main provisions of the Quoted Companies Alliance's Corporate Governance Guidelines for Smaller Quoted Companies. The overarching principle of corporate governance on AIM is to ensure that companies are managed in an efficient, effective and entrepreneurial manner for the benefit of all shareholders over the long term.

The Strategic Investor entered into a Relationship Agreement with the Company since they are the largest shareholder. The Relationship Agreement regulates the relationship between the parties so as to ensure that all transactions and activities between the parties are conducted at arm's-length and on normal commercial terms. Per the terms of the Relationship Agreement, as long as the Strategic Investor owns more than 25% of the Company, they will do everything that is reasonable to ensure that the Company is able to conduct its business independently of the Strategic Investor and will not take any action which would prejudice the Company's independence. The Strategic Investor has agreed that when making decisions relating to the Company, they will act in the best interest of the shareholders as a whole, irrespective of what may be in their own best interest.

The Company established Audit, Remuneration and Nomination Committees. The six NEDs are spread evenly across the three Committees with the NEC serving as a member of the Audit and Remuneration Committees. The Company will hold regular board meetings and the Committees will meet as and when appropriate, however, the Audit and Remuneration Committees will meet at least twice a year. Per the Company's agreement with its AIM Nominated Adviser (Nomad), the Nomad can require the Company to form an AIM Compliance Committee to liaise with them regarding compliance with the AIM Rules for Companies. The Nomad has, however, determined that the establishment of such a committee is not necessary at this time.

### **Accounting Considerations**

The Company is incorporated in the U.K., therefore, it is required to report using IFRS. Since the Company only has one operating subsidiary and all of its expenses are in U.S. Dollars, the U.S. Dollar is the functional currency and was also chosen as the reporting currency.

The U.K. Member Firm of an international accountancy network acted as Auditor and Reporting Accountant. Since the Company's annual audited financial statements were more than nine months old, unaudited, comparative, stub period financials were required. In this case, stub period financials were provided to and for the six months ended June 30<sup>th</sup>.

An unaudited pro forma statement of net assets is never required in connection with an AIM IPO but was provided to illustrate the merger with the Maryland-based company simultaneous with the IPO that provided the Company's leading drug candidate, iclaprim, the conversion into equity and/or the waiver of certain trade and other payables and loans and borrowings, the recharacterization of certain short-term notes into long-term notes, the proceeds from a pre-IPO fundraising and the net proceeds from the IPO.

### **Legal Considerations**

Even though the Company's 'principal place of business' is in the U.S., since the Company is incorporated in the U.K. and its 'place of central management and control' is in the U.K., the three significant differences between U.S. and U.K. corporate law automatically apply as follows:

1. Pre-emption rights (i.e. anti-dilution) – Shareholders may participate in, or the Company has to obtain approval from at least 75% of them for, the issuance of shares for cash of more than 30% of the then outstanding shares during any 12-month period.<sup>3</sup>
2. Notifiable Interests – Shareholders are required to notify the Company of, and the Company is required to publicly announce, holdings at or above the 3% level and whenever a full percentage point is breached in either direction.
3. Takeovers (i.e. mandatory offer) – If any party, or parties acting in concert, accumulates a holding of 30% or more, they must make a cash offer to the other shareholders at the highest price they paid for the Company's shares during the last 12 months.

The IPO was not subject to Regulation S of the U.S. Securities Act of 1933, therefore, the shares are eligible for dematerialization and trading within CREST, the most common electronic system for the holding and transfer of shares in the U.K. As such, it was not necessary to appoint a Depository and create Depository Interests, as would be the case for a company domiciled outside the U.K. or one of its Crown Dependencies, the Channel Islands and the Isle of Man.

### **Other**

Since the Company acquired its leading drug candidate via a merger simultaneous with the IPO, the Company's Nomad required the inclusion of an Experts' Report. The report provided background information on the history and development of the drug and set out the remaining steps necessary to determine the appropriate development pathway, along with the key risks involved in such development.

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<sup>3</sup> Since the Company only raised approximately half of the amount that will be required to conduct the two Phase III trials, this is higher than the 10% level at which AIM-listed companies typically seek an annual standing authorization from their shareholders for the issuance of additional shares for cash. This flexibility increases the certainty and speed of a secondary offering within this authority and reduces transaction costs, since further communications with, and approvals from, shareholders are not required.