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# Motif Bio Plc

**(MTFB-NASDAQ)**

***MTFB: Completes Submission of NDA for Iclaprim…***

Based on our probability adjusted DCF model that takes into account potential future revenues from Iclaprim, MTFB is valued at $28 per share. This model is highly dependent upon continued clinical and commercial success of Iclaprim and will be adjusted accordingly based upon future clinical results and the company's execution.

| | |
|---|---|
| Current Price (06/19/18) | $8.57 |
| **Valuation** | **$28.00** |

## OUTLOOK

Motif Bio Plc recently announced that the company has completed the rolling submission for the New Drug Application (NDA) for iclaprim. The FDA previously informed the company that a small business waiver was granted such that the application fee for the NDA, which totals $2.4 million in 2018, does not need to be paid. We anticipate hearing within 60 days whether the NDA was accepted followed by a 6-month review period, thus the drug could be approved in the first quarter of 2019.

Motif recently presented data at the 28th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID 2018) and the American Society of Microbiology (ASM) Microbe 2018 meeting. An overview of those presentations is included in this report.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$11.84** |
| **52-Week Low** | **$6.97** |
| **One-Year Return (%)** | **9.86** |
| **Beta** | **-0.05** |
| **Average Daily Volume (sh)** | **3,136** |
| **Shares Outstanding (mil)** | **13** |
| **Market Capitalization ($mil)** | **$137** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **43** |
| **Insider Ownership (%)** | **16** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **0.00** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **N/A** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2018 Estimate** | **N/A** |
| **P/E using 2019 Estimate** | **N/A** |

| | |
|---|---|
| **Risk Level** | **High** |
| **Type of Stock** | **Small-Growth** |
| **Industry** | **Med-Biomed/Gene** |

## ZACKS ESTIMATES

**Revenue**
(In millions of $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2017 | 0.0 A | 0.0 A | 0.0 A | 0.0 A | 0.0 A |
| 2018 | 0.0 E | 0.0 E | 0.0 E | 0.0 E | 0.0 E |
| 2019 | | | | | 11.0 E |
| 2020 | | | | | 49.0 E |

**Earnings per ADS**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2017 | -$1.50 A | -$1.50 A | -$1.07 A | -$1.07 A | -$3.87 A |
| 2018 | -$0.45 E | -$0.45 E | -$1.08 E | -$1.09 E | -$2.09 E |
| 2019 | | | | | -$1.85 E |
| 2020 | | | | | -$0.48 E |

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## WHAT'S NEW

**Business Update**

Motif Bio Plc (MTFB) is a biopharmaceutical company focused on the development of antibiotic compounds for difficult to treat bacterial infections. The company's lead asset, iclaprim, is a novel diaminopyrimidine molecule that has completed Phase 3 testing for the treatment of acute bacterial skin and skin structure infections (ABSSSI), with the company announcing positive results from the two studies earlier in 2017. In addition, the U.S. Food and Drug Administration (FDA) has granted iclaprim orphan drug designation (ODD) for the treatment of bacterial infections in patients with cystic fibrosis caused by *Staphylococcus aureus*.

*NDA Submission Completed*

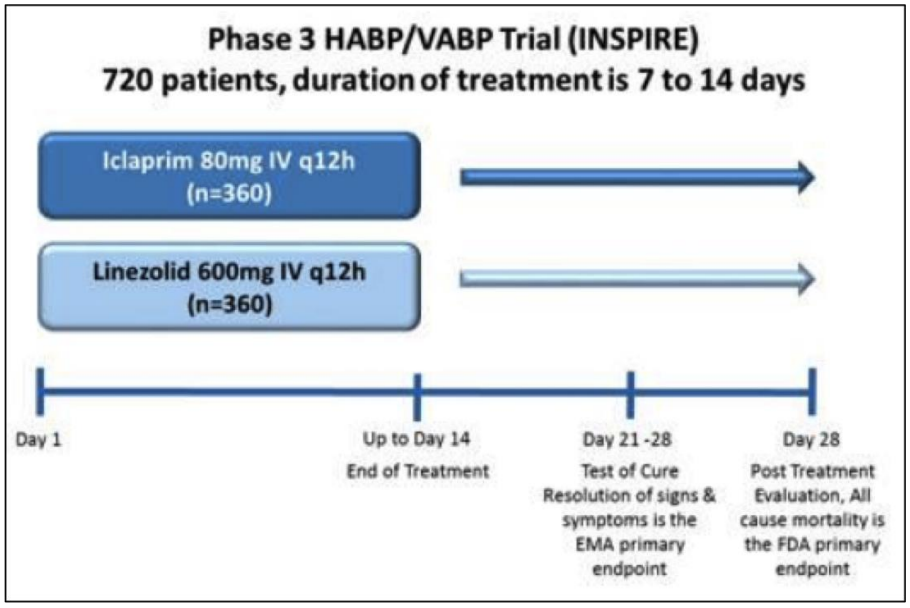
On June 14, 2018, Motif announced the completion of the rolling submission for the New Drug Application (NDA) for iclaprim with the U.S. FDA. Previously, the FDA informed the company that it was granted a small business waiver and that the NDA application fee, which is $2.4 million in 2018, will not have to be paid.

The company was able to use a rolling NDA submission, in which the company submits portions of the NDA has they are completed, due to the fact that iclaprim was granted Fast Track Designation. In addition, iclaprim has been designated a Qualified Infectious Disease Product (QIDP), which allows for the drug to receive a Priority Review of up to six months instead of the typical 10 months. Lastly, QIDP designation also makes iclaprim eligible for 10 years of market exclusivity; five years due to being a new chemical entity and an additional five years from QIDP designation. We anticipate a PDUFA date for iclaprim in the first quarter of 2019.

*Looking to Initiate Phase 3 in HABP/VABP in 2018*

While the company's focus remains on iclaprim in ABSSSI and getting the NDA submitted, the company is also planning for a Phase 3 randomized, double blind, comparator study to determine the safety and efficacy of iclaprim in hospital acquired bacterial pneumonia (HABP) and ventilator associated bacterial pneumonia (VBAP) compared with linezolid. HBAP refers to a pneumonia that is acquired following at least 48 hours in the hospital while VABP refers to pneumonia that develops 48 hours or more after mechanical ventilation.

Treatment with both iclaparim and linezolid is expected to be 7 to 14 days. A total of approximately 720 subjects will be studied with a non-inferiority margin of -10%. The primary endpoint of the study will be all cause mortality at Day 28, with a key secondary endpoint of clinical cure at one to two weeks after ending antibiotic treatment. The study should satisfy requirements for both FDA and EMA regulatory approval. An outline of the study is provided in the following graphic.




*Source*: Motif Bio Plc

Motif has previously presented data showing that iclaprim's concentration in epithelial lining fluid (ELF) and alveolar macrophages (AM) is elevated in comparison to serum levels, as shown in the following chart following dosing of healthy volunteers. The concentration of iclaprim in ELF and AM was 20 to 30 times the serum concentration, which could lead to positive outcomes for treating lung infections.

| Antibiotic | Dose | Epithelial lining fluid (mg/L) | Alveolar macrophages (mg/L) | Serum (mg/L) | ELF/serum concentration | AM/serum concentration |
|---|---|---|---|---|---|---|
| Iclaprim | 1.6 mg/kg IV, single dose | 40.9 | 67.7 | 1.8 | 22.7 | 37.6 |
| Linezolid | 600 mg q12h PO, 5 doses | 622.8 | 27.2 | 190.0 | 3.3 | 0.14 |
| Vancomycin | 1 g q12h IV, 9 doses | 92 | 926 | 367 | 0.25 | 2.5 |

*Source*: Motif Bio Plc

Arpida (which was developing iclaprim prior to Motif) conducted a double blind, randomized, dose ranging Phase 2 proof of concept study in patients with HABP, including VABP. A total of 70 patients were randomized 1:1:1 to receive 0.8 mg/kg iclaprim, 1.2 mg/kg iclaprim, or 1 g vancomycin either two or three times daily. Results showed a clinical cure rate of 73.9% (17/23 patients) with 0.8 mg/kg iclaprim, 62.5% (15/24 patients) with 1.2 mg/kg iclaprim, and 52.2% (12/23 patients) with 1 g vancomycin. Results are summarized in the table below.

Phase 2 Trial of Iclaprim in Patients with HBAP (N=70)

| | 0.8 mg/kg iclaprim | 1.2 mg/kg iclaprim | 1 g vancomycin |
|---|---|---|---|
| Intent to Treat Population (N=) | 23 | 24 | 23 |
| Clinical Cure (N=) | 17 | 15 | 12 |
| *% Clinical Cure* | *73.9%* | *62.5%* | *52.2%* |
| Fatalities within 28 days | 2 | 3 | 5 |
| % Death rate | *8.7%* | *12.5%* | *21.7%* |

*Source:* Motif Bio Plc

The initiation of the INSPIRE Phase 3 trial of iclaprim in patients with HABP and VABP will occur if and when additional funding is obtained.

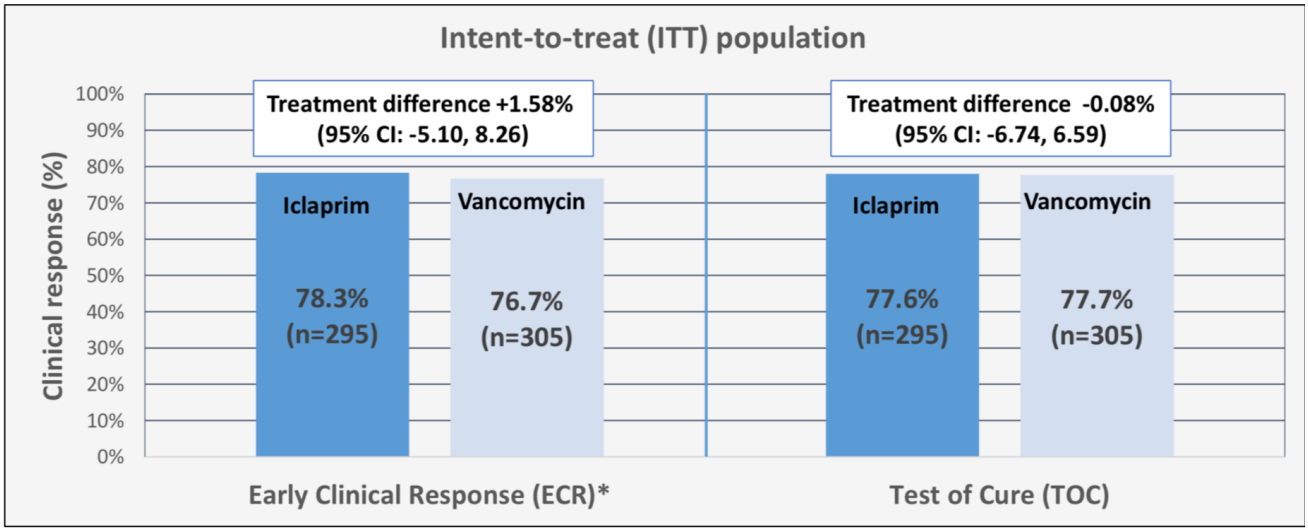
*Presentations at ECCMID 2018*

Motif recently had three presentations related to iclaprim at the 28th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID 2018).

**REVIVE-2: A phase 3, Randomized, double-blind, multicenter study to evaluate the safety and efficacy of intravenous Iclaprim versus Vancomycin in the treatment of acute bacterial skin and skin structure infections suspected or confirmed to be due to Gram-positive pathogens**

Dr. Thomas Holland gave a presentation on the results from REVIVE-2, the Phase 3 clinical trial of iclaprim for the treatment of acute bacterial skin and skin structure infections (ABSSSI). Dr. Holland began his presentation by providing an overview of the advantages for iclaprim, including the fact that its targeted to treat Gram-positive infections (including those caused by MRSA), its concentration is highest in areas of infection (including skin and lung), there have been no reports of nephrotoxicity (in contrast to vancomycin), it has an optimized fixed dosing schedule, it has demonstrated clinical efficacy in two Phase 3 clinical trials, and it uses an underutilized mechanism of action targeting dihydrofolate reductase.

The following slide shows the results for both early clinical response (ECR, defined by FDA as ≥20% reduction in lesion size at 48-72 hours [early time point, ETP] compared to baseline) and test of cure (TOC). Iclaprim was within the -10% non-inferiority margin compared to vancomycin for each endpoint.




*Source*: Holland, 2018

The following slide shows the safety results from the trial. Iclaprim was well tolerated with similar levels of study drug related treatment-emergent adverse events (TEAEs) and TEAE related serious AEs. Of note is the large difference in mean serum creatinine change from baseline to TOC for iclaprim (0.7) compared to vancomycin (7.7), again showing the lack of nephrotoxicity for iclaprim.

| | Iclaprim N=299 | Vancomycin N=302 |
|---|---|---|
| Study drug related TEAEs | 42 (14.0%) | 39 (12.9%) |
| TEAE related serious AEs | 14 (4.7%) | 12 (4.0%) |
| Mean QTcF prolongation msec (SD) | 9.9 (14.6) | 3.8 (16.3) |
| Mean serum creatinine change from baseline to TOC umol/L (SD) | 0.7 (18.0) | 7.7 (39.8) |
| Mean serum creatinine change from baseline to TOC, mg/dL (SD) | 0.008 (0.20) | 0.09 (0.45) |
| Deaths | 0 | 1 (0.3%) |
| TEAEs >4% | | |
| Nausea | 17 (5.7%) | 17 (5.6%) |
| Infusion site extravasation | 13 (4.3%) | 12 (4.0%) |
| Headache | 7 (2.3%) | 13 (4.3%) |
| ***75% of adverse events in REVIVE-2 categorized as mild*** | | |

*Source*: Holland, 2018

These data support the use of iclaprim for the treatment of ABSSSI suspected to be due to the Gram-positive pathogens as the drug was safe and efficacious with few drug-related AEs.

**Potential Cost Savings Opportunities with Targeted Use of Iclaprim (ICL) Compared to Vancomycin (VAN) among Hospitalized Patients with Acute Bacterial Skin and Skin Structure Infections Due to Potential Avoidance of VAN-Associated Acute Kidney Injury V-A AKI.**

This study involved the generation of a cost-minimization model from the hospital perspective to estimate the potential cost savings by replacing VAN with iclaprim for the treatment of SSSI. VAN is currently the most prescribed antibiotic for the treatment of ABSSSI, however acute kidney injury (AKI) is a relatively common side effect, occurring in 9.2% of patients (based on the rate seen in hospitalized patients at the Veterans Affairs Medical Center). The following table shows the overall cost of treating a patient with vancomycin-associated AKI depending upon the daily hospitalization cost and whether specialty physician consultations are needed. These costs ranged from $8,377 to $19,464, thus replacing vancomycin with iclaprim would result in significant cost savings for hospitals due to the avoidance of vancomycin-associated AKI.

**Daily Costs Of Hospitalization**

| Daily Hospitalization Cost | $1,585.69/day | $2,000/day | $2,500/day | $3,000/day |
|---|---|---|---|---|
| Vancomycin-associated AKI only | $8,377 | $10,448 | $12,948 | $15,448 |
| Vancomycin-associated AKI and specialty physician consultation | $10,802 | $12,873 | $15,373 | $17,873 |
| Vancomycin-associated AKI, specialty physician consultation and acute dialysis | $12,393 | $14,464 | $16,964 | $19,464 |
| | | | | |
| Overall neutral iclaprim cost-threshold over vancomycin | $172.89 | $200.12 | $232.98 | $265.83 |

*Source*: Patel *et al.*, 2018

**Surveillance of iclaprim activity: *in vitro* susceptibility of *Staphylococcus aureus* resistant to clindamycin/tetracycline and beta-haemolytic streptococci resistant to macrolides/tetracyclines among skin and skin-structure pathogens colleted during 2015-2016 from Europe and North America**

This study was performed to determine the susceptibility of skin and skin structure pathogens (*S. aureus* and beta-hemolytic streptococci) to iclaprim and comparator antibiotics that were collected from Europe and North America from 2015-2016. A total of 618 isolates of *S. aureus* and 313 beta-hemolytic streptococci were tested. The following table shows the iclaprim MIC values for *S. aureus* strains resistant to clindamycin (CLI-R) and tetracycline (TET-R) along with MIC values for streptococci, including those resistant to macrolides (AZI-R) and tetracyclines. Iclaprim was active against the majority of isolates ($MIC_{90}$ value for all strains tested = 0.12 mg/L), although some MICs were higher for certain resistant subgroup phenotypes. MIC values for streptococci were only slightly changed for resistant subgroups.

| Phenotype | n | $MIC_{50}$ | $MIC_{90}$ |
|---|---|---|---|
| *S. aureus* | 618 | 0.03 | 0.12 |
| *S. aureus* CLI-R | 106 | 0.03 | 16 |
| *S. aureus* TET-R | 48 | 0.06 | >32 |
| MRSA CLI-R | 94 | 0.03 | 16 |
| MRSA TET-R | 31 | 0.06 | >32 |
| MSSA CLI-R | 12 | 0.06 | 16 |
| MSSA TET-R | 17 | 0.06 | >32 |
| BHS | 313 | 0.03 | 0.25 |
| BHS AZI-R | 82 | 0.06 | 0.5 |
| BHS TET-R | 121 | 0.06 | 0.5 |

*Source*: Huang *et al.*, 2018

The results of this experiment show that iclaprim was active against a majority of these isolates, including some that were resistant to other antibiotics. Continued surveillance of clinical isolates will occur to monitor for resistance to iclaprim, and molecular characterization of the subgroups with higher MIC values may be necessary to determine any potential changes to those strains DHFR.

*Presentations at ASM 2018*

Motif presented two posters at ASM 2018 on pooled analysis of the REVIVE-1 and REVIVE-2 trials, with one poster focused on efficacy results and the other on safety results. The combined results were also published in the *International Journal of Antimicrobial Agents* (Huang *et al*., 2018). The following two tables show the combined efficacy and safety results demonstrating that iclaprim was non-inferior to the standard of care vancomycin and was safe and well tolerated.

| | REVIVE-1 | | REVIVE-2 | | Combined REVIVE-1/2 | |
|---|---|---|---|---|---|---|
| | Iclaprim (N=298) | Vancomycin (N=300) | Iclaprim (N=295) | Vancomycin (N=305) | Iclaprim (N=593) | Vancomycin (N=605) |
| Early Clinical Response, n (%) | 241 (80.9) | 243 (81.0) | 231 (78.3) | 234 (76.7) | 472 (79.6) | 477 (78.8) |
| % Difference (iclaprim-vancomycin) | -0.13 | | 1.58 | | 0.75 | |
| 95% CI | -6.42, 6.17 | | -5.10, 8.26 | | -3.84, 5.35 | |

*Source*: Huang *et al*., 2018

| | REVIVE-1 | | REVIVE-2 | | Combined REVIVE-1/2 | |
|---|---|---|---|---|---|---|
| | Iclaprim (N=293) | Vancomycin (N=297) | Iclaprim (N=299) | Vancomycin (N=302) | Iclaprim (N=592) | Vancomycin (N=599) |
| **Patients with:** | | | | | | |
| Any TEAE | 151 (51.5) | 128 (43.1) | 140 (46.8) | 133 (44.0) | 291 (49.2) | 261 (43.6) |
| Study Drug Related TEAEs | 57 (19.5) | 53 (17.8) | 42 (14.0) | 39 (12.9) | 99 (16.7) | 92 (15.4) |
| TEAE with Discontinuation of Study Drug | 8 (2.7) | 13 (4.4) | 16 (5.4) | 17 (5.6) | 24 (4.1) | 30 (5.0) |
| SAEs | 9 (3.1) | 14 (4.7) | 16 (5.4) | 14 (4.6) | 25 (4.2) | 28 (4.7) |
| Deaths | 0 | 2 (0.7)[4] | 0 | 1 (0.3) | 0 | 3 (0.5) |
| **MedDRA Preferred Terms:** | | | | | | |
| Nausea | 29 (9.9) | 17 (5.7) | 17 (5.7) | 17 (5.6) | 46 (7.8) | 34 (5.7) |
| Headache | 30 (10.2) | 23 (7.7) | 7 (2.3) | 13 (4.3) | 37 (6.3) | 36 (6.0) |
| Cellulitis | 9 (3.1) | 5 (1.7) | 18 (6.0) | 9 (3.0) | 27 (4.6) | 14 (2.3) |
| Infusion site extravasation | 14 (4.8) | 12 (4.0) | 13 (4.3) | 12 (4.0) | 27 (4.6) | 24 (4.0) |
| Skin bacterial infection | 15 (5.1) | 9 (3.0) | 8 (2.7) | 2 (0.7) | 23 (3.9) | 11 (1.8) |
| Vomiting | 14 (4.8) | 15 (5.1) | 7 (2.3) | 7 (2.3) | 21 (3.5) | 22 (3.7) |
| Pyrexia | 12 (4.1) | 12 (4.0) | 7 (2.3) | 5 (1.7) | 19 (3.2) | 17 (2.8) |
| Fatigue | 18 (6.1) | 9 (3.0) | 0 | 4 (1.3) | 18 (3.0) | 13 (2.2) |
| Diarrhea | 5 (1.7) | 14 (4.7) | 8 (2.7) | 11 (3.6) | 13 (2.2) | 25 (4.2) |
| AST increased | 6 (2.0) | 7 (2.4) | 6 (2.0) | 5 (1.7) | 12 (2.0) | 12 (2.0) |
| Peripheral edema | 8 (2.7) | 9 (3.0) | 4 (1.3) | 3 (1.0) | 12 (2.0) | 12 (2.0) |
| Alanine aminotransferase increased | 6 (2.0) | 5 (1.7) | 5 (1.7) | 7 (2.3) | 11 (1.9) | 12 (2.0) |
| Anaemia | 5 (1.7) | 2 (0.7) | 6 (2.0) | 6 (2.0) | 11 (1.9) | 8 (1.3) |
| Pain in extremity | 6 (2.0) | 3 (1.0) | 5 (1.7) | 2 (0.7) | 11 (1.9) | 5 (0.8) |
| Hypertension | 3 (1.0) | 2 (0.7) | 7 (2.3) | 5 (1.7) | 10 (1.7) | 7 (1.2) |
| Hypokalaemia | 1 (0.3) | 2 (0.7) | 6 (2.0) | 11 (3.6) | 7 (1.2) | 13 (2.2) |

*Source*: Huang *et al*., 2018

## Financial Update

In May 2018, the company raised gross proceeds of £10 million ($13.5 million) through a conditional placing with new and existing investors. The company exited 2017 with approximately $22.7 million and with the most recent infusion of capital we believe the company is in strong financial shape heading into the second half of 2018.

Depending upon which commercialization pathway the company decides to go will dictate how much additional capital will be necessary to launch iclaprim, if approved. Motif is currently developing plans to commercialize the drug itself as well as speaking with a number of potential partners. Approximately 1,000-1,200 hospitals in the U.S. account for 70% of the vancomycin prescriptions, which are concentrated in the population centers in the country, thus the company has a good sense of how many medical science liaisons and account managers would be necessary to launch iclaprim as well as making it feasible to hire a contract sales organization to target those institutions. The problem with this strategy is it is relatively capital intensive and not very efficient since Motif only has a single asset at this point.

Alternatively, Motif is examining the potential to partner with a company that is in a similar situation where an NDA has been or will soon be filed for either an antibiotic or another type of drug to sell in the hospital setting. In addition, Motif is in discussions with revenue generating companies who are looking to expand their portfolio. From an efficiency and capital needs perspective it makes more sense for Motif to partner, however only if it is under terms that make sense for both parties. If a partner cannot be found, the company is fully prepared to "go it alone" and build a commercial organization.

## Conclusion

We're glad to see that Motif has completed the NDA filing for iclaprim on schedule before the end of the second quarter of 2018. The FDA now has 60 days to determine whether to accept the NDA filing, and if it does it will assign a 6-month PDUFA date based on iclaprim receiving Fast Track designation, which we anticipate being in the first quarter of 2019.

There are an estimated 3.6 million people hospitalized with ABSSSI every year. We conservatively estimate that 20% of patients have renal insufficiency, based on published data (Halilovic *et al*., 2012). We believe iclaprim could attain peak market share among these patients of 20%. We model for a full course of treatment costing $3000 and an inflation rate of 2%, which leads to peak sales of approximately $500 million in the U.S. Outside the U.S., we believe Motif will sign a commercialization agreement that will result in an average 15% royalty on net sales, which we estimate will peak at approximately $225 million. Using a 90% probability of approval and a 15% discount rate leads to a net present value for iclaprim in ABSSSI of $475 million. After factoring in the company's cash position, potential cash from the exercise of outstanding warrants, and dividing by the fully diluted ADS share count of 18.6 million leads to a valuation of $28 per share. The stock continues to trade at a significant discount to our valuation, thus offering investors plenty of upside at the current price.

## PROJECTED FINANCIALS

**Motif Bio Plc**
Income Statement

| Motif Bio Plc | 2017 A | 1H18 | 2H18 | 2018 E | 2019 E | 2020 E |
|---|---|---|---|---|---|---|
| **Iclaprim (ABSSSI)** | $0 | $0 | $0 | $0 | $11 | $49 |
| *YOY Growth* | | - | - | | | |
| **Iclaprim (HABP)** | $0 | $0 | $0 | $0 | $0 | $0 |
| *YOY Growth* | | - | - | | | |
| **Iclaprim (CF)** | $0 | $0 | $0 | $0 | $0 | $0 |
| *YOY Growth* | | - | - | | | |
| **Grants & Collaborative Revenue** | $0 | $0 | $0 | $0 | $0 | $0 |
| *YOY Growth* | | - | - | | | |
| **Total Revenues** | **$0** | **$0** | **$0** | **$0** | **$11** | **$49** |
| *YOY Growth* | | - | - | | | |
| Cost of Sales | $0 | $0 | $0 | $0 | $2 | $8 |
| *Product Gross Margin* | | - | - | | | |
| Research & Development | $29.5 | $6.0 | $8.0 | $14.0 | $18.0 | $20.0 |
| General & Administrative | $8.5 | $4.4 | $8.0 | $12.4 | $25.0 | $30.0 |
| Other Expenses | $0 | $0 | $0 | $0 | $0 | $0 |
| Operating Income | ($38.02) | ($10.4) | ($16.0) | ($26.4) | ($34.0) | ($9.0) |
| *Operating Margin* | | - | - | | | |
| Non-Operating Expenses (Net) | ($6.8) | ($1.5) | ($1.5) | ($3.0) | ($3.0) | ($3.0) |
| Pre-Tax Income | ($44.8) | ($11.9) | ($17.5) | ($29.4) | ($37.0) | ($12.0) |
| Income Taxes Paid | $0 | $0 | $0 | $0 | $0 | $0 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* |
| **Net Income** | **($44.8)** | **($11.9)** | **($17.5)** | **($29.4)** | **($37.0)** | **($12.0)** |
| *Net Margin* | | - | - | | | |
| **Net Loss per Share** | **($0.19)** | **($0.05)** | **($0.06)** | **($0.10)** | **($0.09)** | **($0.02)** |
| **Net Loss per ADS** | **($3.87)** | **($0.90)** | **($1.17)** | **($2.09)** | **($1.85)** | **($0.48)** |
| *YOY Growth* | | - | - | | | |
| Basic Shares Outstanding | 231.5 | 264.0 | 300.0 | 282.0 | 400.0 | 500.0 |
| ADS Oustanding | 11.6 | 13.2 | 15.0 | 14.1 | 20.0 | 25.0 |

*Source: Zacks Investment Research, Inc.* *David Bautz, PhD*

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## HISTORICAL STOCK PRICE




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