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Midatech Pharma Plc

(MTP-NASDAQ)

MTP: Lead Candidates Set to Enter the Clinic; U.S. Product Sales Up ~30% in 2017

Based on our probability adjusted DCF model that takes into account potential future revenues from GNP, Q-Sphera, and NI platform products along with revenues from Midatech Pharma US, MTP is valued at $6.50 per share. This model is highly dependent upon continued clinical and commercial success and will be adjusted accordingly based upon future clinical results and the company's execution.

Current Price (03/07/18)	$0.97
Valuation	**$6.50**

OUTLOOK

Midatech Pharma Plc (MTP) was recently approved to initiate a clinical trial of MTX110 in patients with DIPG, a fatal childhood brain cancer. We believe dosing will initiate soon with topline data available at the end of 2019. In addition, the EMA granted MTD119 orphan drug designation (ODD) for the treatment of liver cancer

The company recently provided an update on unaudited financial results for 2017, which showed an approximately 30% increase in U.S. product revenues and total revenues of at least £7.4 million, which is right in line with our estimate.

SUMMARY DATA

52-Week High	**$2.95**
52-Week Low	**$0.84**
One-Year Return (%)	**-65.48**
Beta	**0.54**
Average Daily Volume (sh)	**14,143**
Shares Outstanding (mil)	**31**
Market Capitalization ($mil)	**$30**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
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	**-3.2**
P/E using 2019 Estimate	**-3.2**

Risk Level	**High,**
Type of Stock	**Small-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of £)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	1.8 A	2.0 A	1.4 A	1.4 A	5.6 A
2017	1.5 A	1.9 A	2.0 E	2.0 E	7.4 E
2018					9.0 E
2019					10.7 E

Earnings per share
(In £)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-0.61 A	-0.70 A	-0.95 A	-1.20 A	-0.56 A
2017	-0.09 A	-0.10 A	-0.06 E	-0.07 E	-0.31 E
2018					-0.24 E
2019					-0.24 E

WHAT'S NEW

Business Update

Set to Initiate Clinical Trial of MTX110 in DIPG

On January 16, 2018, Midatech Pharma Plc (MTP) announced that the U.S. Food and Drug Administration (FDA) approved the investigational new drug (IND) application to initiate a clinical trial of MTX110 in patients with diffuse intrinsic pontine glioma (DIPG). We anticipate the first patient being dosed soon with topline results available at the end of 2019. The efficacy endpoint for the Phase II component will be Overall Survival (OS) at 12 months, conducted at the recommended Phase 2 dose. To date, MTX110 has been used on a compassionate use basis to treat five patients, where the drug was well tolerated. Treating DIPG represents a potential $50-$100 million worldwide opportunity based on the available patient population and potential for orphan drug pricing.

The active compound in MTX110 is the poorly soluble hydroxamic acid drug panobinostat, a histone deacetylase inhibitor (HDACi), which until recently could not be formulated for parenteral administration. Midatech's nano inclusion (NI) technology enabled the aqueous solubility of this class of small molecule cancer therapeutic, which expands parenteral delivery options that in turn are expected to improve the safety and efficacy of the treatment. Midatech in-licensed the drug panobinostat for use in treating DIPG for an upfront payment of $1 million and potential future milestone payments. Panobinostat was developed by Novartis and approved in 2015 for the treatment of multiple myeloma.

DIPG

DIPG is a highly infiltrative brainstem high grade glioma that occurs mostly in children. The tumors are aggressively infiltrative such that cancer tissue typically cannot be differentiated from normal brain tissue. The overall median survival of children with DIPG is approximately 9 months and remains unchanged despite decades of clinical trial research. The only standard of care is palliative focal radiotherapy, but this has minimal effect on survival and essentially all children die of this disease. Surgical resection is unavailable due to the location of the tumor in the brainstem. New therapeutic strategies are urgently needed. Approximately 1,000 individuals worldwide are diagnosed with DIPG each year.

Panobinostat

Panobinostat (Farydak®) is a potent, nonselective histone deacetylase inhibitor. It was selected as a potential treatment for DIPG following the screening of 83 drugs against 14 patient-derived DIPG cell cultures (Grasso *et al.*, 2015). The drugs were selected by pediatric neurooncologists as either promising targeted agents or traditional chemotherapeutic agents used in pediatric brain tumor therapy. Panobinostat was effective against 12/16 patient-derived DIPG cell cultures. Although effective in both *in vitro* and *in vivo* models, panobinostat does not cross the blood-brain barrier effectively thus necessitating an alternate means of delivery. Direct delivery of MTX110, the soluble form of panobinostat, bypasses the blood brain barrier and ensures adequate drug exposure to tumor cells. MTX110 molecular targeting and intratumoral delivery provides significant potential for treatment of DIPG.

Convection-Enhanced Delivery

One of the many difficulties in treating tumors of the central nervous system is getting enough drug into the tumor for a sufficient time to allow for a therapeutic effect. Many drugs do not effectively pass through the blood-brain barrier, and for these compounds direct injection into the tumor is commonly used. However, even with direct administration, limited diffusion of drug through the tumor and brain interstitium means only a small volume of tissue surrounding the injection site is effectively treated.

Convection-enhanced delivery (CED) is a method used to deliver drugs into the brain through a pressure gradient in order to saturate the extracellular fluid compartment (Bobo *et al.*, 1994). In contrast to diffusion, which depends entirely upon a concentration gradient to distribute the molecules, the use of hydraulic pressure in CED allows for homogenous distribution over large distances by displacing the interstitial fluid. Since being shown to be safe for the delivery of drugs to the brainstem (Sandberg *et al.*, 2002), CED has been tested in a number of adult malignant gliomas, however there are no completed CED trials for DIPG with a few clinical trials ongoing (Zhou *et al.*, 2017).

Orphan Drug Designation for MTD119

On February 28, 2018, Midatech announced that the European Medicines Agency (EMA) granted Orphan Drug Designation (ODD) for MTD119, the company's advanced liver cancer drug candidate. The ODD program is intended to assist in the development of drugs for the treatment of diseases or disorders that affect fewer than 5 in 10,000 people in the EU. In addition to development assistance, drugs granted approval under the ODD program are conferred with 10 years of market exclusivity.

MTD119 is the company's lead development product utilizing the gold nanoparticle (GNP) technology. It is being developed for the treatment of hepatocellular carcinoma and utilizes mertansine (DM1) as a cytotoxic agent. DM1 is a derivative of maytansine that is currently utilized in the approved antibody-drug conjugate (ADC) therapy Kadcyla®. In preclinical models, Midatech has reported the GNP-conjugation allows otherwise lethal doses of mertansine to be administered with peak reduction in tumor growth more than 6x greater than the current standard of care, sorafenib (Nexavar®). The company has initiated an IND-enabling program to study drug metabolism, pharmacokinetics, dosing, and toxicity of MTD119 which, if successful, will be followed by a first in human study set to initiate in the second half of 2018 or early 2019.

Liver Cancer

Hepatocellular carcinoma (HCC) is the most common form of primary liver cancer, with over 700,000 individuals affected worldwide, and is the third leading cause of cancer death in the world (ACS). HCC is relatively rare in the U.S. (approximately 35,000 individuals in the U.S. will be diagnosed with HCC in 2017) and other countries where hepatitis infections are not widespread, as most cases of HCC are due to hepatitis infection (both hepatitis B and C). Most cases of liver cancer in countries with low hepatitis rates are due to metastasis of other primary tumors.

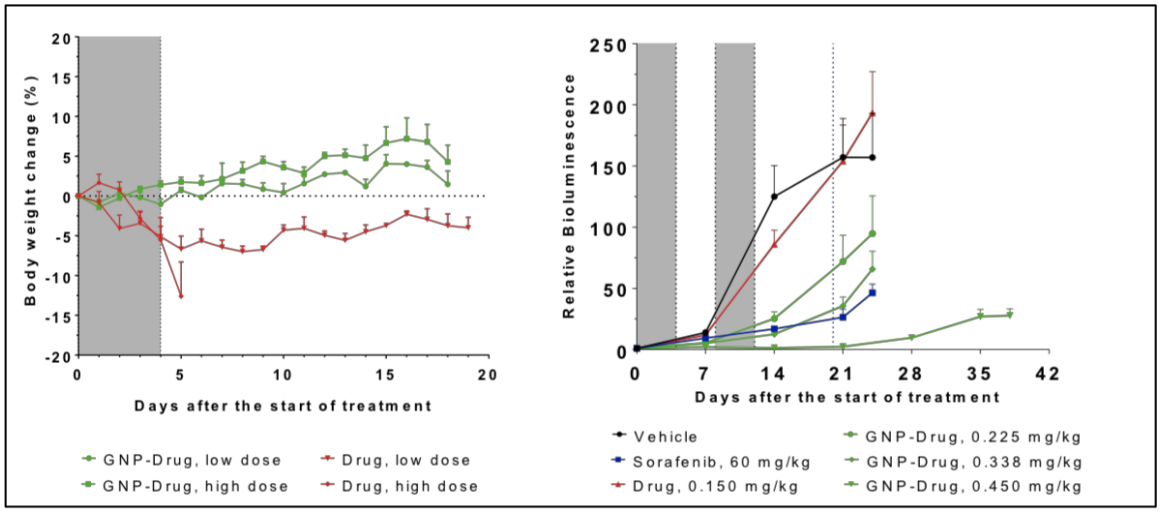
Survival time for patients with HCC is entirely dependent on how advanced the disease is when first diagnosed. If found early, liver transplantation offers a potential curative therapy, with 5-year overall survival of 75% and a tumor recurrence rate of less than 15% (Mazzaferro *et al*., 1996). Patients with small tumors and little underlying cirrhosis are eligible for surgical resection. Additional treatment options include local ablative therapies such as radio-frequency ablation (RFA), trans-arterial chemo-embolization (TACE), percutaneous ethanol ablation, and radioembolization.

There is no cure for advanced HCC; thus, there exists a significant unmet need for an effective therapy. The current standard of care for advanced HCC is sorafenib, which was approved based upon the results of two randomized, double blind, placebo controlled clinical trials where survival was extended by between 2 – 3 months (Llovet *et al*., 2008, Cheng *et al*., 2009). Sales of Nexavar® totaled $963 million in 2016, with approximately 80% of those revenues derived from the treatment of HCC (EvaluatePharma).

For patients refractory to sorafenib, the FDA recently approved regorafenib (Stivarga®) based on the outcome of a Phase 3 clinical trial of 573 patients with HCC that had progressed after treatment with sorafenib (Bruix *et al*., 2017). Similar to sorafenib, regorafenib was shown to extend median overall survival by 2.8 months compared to placebo.

HCC Targeted GNP

A GNP construct for targeting HCC was developed based on a gold nanoparticle core covered with a combination of carbohydrate galactose ligands and the potent tubulin inhibitor DM1 (mertansine), which inhibits microtubule assembly and disrupts mitosis in malignant cells. Preclinical models have shown a clear impact of the GNP technology on the safety and efficacy of DM1. In preclinical safety models, doses achieved with MTD119 (GNP bound DM1) were up to three times higher than those achieved with DM1 alone. The below left figure shows mice treated with DM1 alone at 150 µg/kg tolerated the drug very poorly (as exhibited by weight loss), whereas mice treated with GNP-DM1 at 450 µg/kg tolerated the drug very well (increasing weight during the study). The MTD119 construct was then tested in preclinical efficacy models, where it was tested in animals implanted with human liver tumor cells. The below right figure shows the superiority of MTD119 versus the current standard of care sorafenib, as well as versus DM1 alone. The only group of animals that completed the study was the one treated with high dose MTD119; mice treated with sorafenib or DM1 alone did poorly and did not complete the study. These findings likely reflect the impact the GNP technology has on DM1, including altered biodistribution, targeted efficacy, and reduced off target side effects.



Source: Midatech Pharma Plc

Financial Update

On February 14, 2018, Midatech reported preliminary, unaudited financial results for 2017. Total revenues for the twelve months ended Dec. 31, 2017 are expected to be at least £7.4 million, compared to £6.9 million for 2016. This is right in line with our estimate. Of the £7.4 million in revenue, £6.7 million was derived from U.S. product sales, an increase of 29% over the previous year. We believe the company's U.S. operations were break-even for the second half of 2017. Net cash at the end of 2017 was £13.2 million. Earlier this year, the company announced a four-year senior secured loan agreement with MidCap Financial for up to $15 million. The company has received the first tranche of $7 million, with the issuance of additional funds being contingent upon clinical development milestones for MTD201 and MTX110. We estimate the company has sufficient capital to fund operations into 2019.

Valuation

Midatech's three proprietary drug delivery technologies (Q-Sphera for sustained release of already marketed products, Midacore gold nanoparticles (GNP) for targeted delivery, and Nano Inclusion (NI) for local delivery) help differentiate it from other specialty pharmaceutical companies and the potential quick path to market for MTD201 and MTX110 could deliver additional revenues beginning in just a few years. The company is further differentiated through its U.S. based sales force, which will allow the company to capture the full value of any approved products without the need to partner with a larger pharmaceutical company for sales in the U.S. We're pleased to see the company's commercial operations continuing to grow in line with our expectations, as well as achieving break even status in the second half of 2017. Our valuation for Midatech, which is derived from expected future cash flows from the commercial group, MTD201, MTX110, and MTD119, is $6.50 per share.

PROJECTED FINANCIALS

Midatech Plc
Income Statement

Midatech Pharma Plc (in millions of £)	2016 A	1H A	2H E	2017 E	2018 E	2019 E
Midatech Pharma US	£5.6	£3.0	£3.7	£6.7	£8.5	£10.2
MTX110 - DIPG Glioma	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0
MTD201 - Acromegaly and Carcinoma	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0
MTD119 - Liver cancer	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0
MTR103 - Glioblastoma	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0
Grants & Collaborative Revenue	£1.3	£0.4	£0.3	£0.7	£0.5	£0.5
Total Revenues	**£6.9**	**£3.4**	**£4.0**	**£7.4**	**£9.0**	**£10.7**
Cost of Sales	£0.7	£0.3	£0.4	£0.7	£0.9	£1.3
Product Gross Margin	-	-	-			
Research & Development*	£6.7	£7.1	£4.4	£11.5	£12.0	£14.0
Distribution Costs, Sales and Marketing	£9.5	£4.1	£4.5	£8.6	£10.0	£11.0
Administrative Costs*	£9.2	£1.9	£2.0	£3.9	£4.0	£5.0
Impariment of Intangible Assets	£11.4	£0.0	£0.0	£0.0	£0.0	£0.0
Other Expenses	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0
Operating Income	-£30.6	-£10.0	-£7.3	-£17.3	-£17.9	-£20.6
Operating Margin	-	-	-	-	-	-
Non-Operating Expenses (Net)	£1.26	£0.36	-£0.20	£0.16	£0.01	£0.01
Pre-Tax Income	-£29.3	-£9.7	-£7.5	-£17.2	-£17.9	-£20.6
Income Taxes Paid	-£9.2	-£0.6	-£0.7	-£1.3	-£1.0	-£1.0
Net Income	**-£20.2**	**-£9.0**	**-£6.8**	**-£15.8**	**-£16.9**	**-£19.6**
Net Margin	-	-	-	-	-	-
Exchange Gain/Losses	£3.23	-£0.15	-£0.10	-£0.25	£0.00	£0.00
Total Comprehensive Gain/Loss	**-£16.9**	**-£9.2**	**-£6.9**	**-£16.1**	**-£16.9**	**-£19.6**
Net Loss per Share	**-£0.56**	**-£0.19**	**-£0.13**	**-£0.31**	**-£0.24**	**-£0.24**
YOY Growth	-	-	-	-	-	-
Basic Shares Outstanding	36.1	48.7	54.0	51.3	70.0	80.0

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

*Note: 1H17 R&D and Admin Costs changed to reflect reallocation of costs for future time periods

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