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Midatech Pharma Plc

(MTP-NASDAQ)

MTP: Strategic Refocusing to Pure-Play R&D Company; Pivotal Study of MTD201 to Commence 2H19…

Based on our probability adjusted DCF model that takes into account potential future revenues from Q-Sphera, MidaSolve and MidaCore platform products, MTP is valued at $10.00 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 (05/09/19)	$2.09
Valuation	**$10.00**

OUTLOOK

Midatech Pharma Plc (MTP) underwent a transformation to a pure-play R&D company in 2018 and is now fully focused on advancing its R&D pipeline through clinical testing and to approval. The company successfully completed a Phase 1 study of MTD201 in 2018 and will be initiating a pivotal trial in the second half of 2019, with an expected regulatory filing in 2021. The safety portion of the MTX110 trial in patients with DIPG will be concluding soon, with the efficacy portion to commence shortly thereafter. Encouraging results could lead to accelerated approval, as there are currently no treatment options for DIPG patients.

Midatech secured substantial funding in late 2018/early 2019 and we estimate the company has sufficient capital to fund operations through the first quarter of 2020.

SUMMARY DATA

52-Week High	**$9.55**
52-Week Low	**$1.08**
One-Year Return (%)	**-72.86**
Beta	**3.02**
Average Daily Volume (sh)	**2,030,928**
Shares Outstanding (mil)	**21**
Market Capitalization ($mil)	**$41**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**81**
Insider Ownership (%)	**5**
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-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of £)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	0.2 A	0.3 A	0.7 A	0.7 A	1.9 A
2019	0.2 E	0.3 E	0.2 E	0.3 E	1.0 E
2020					1.0 E
2021					1.0 E

Earnings per share
(In £)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-0.04 A	-0.05 A	-0.04 A	-0.04 A	-0.17 A
2019	-0.01 E	-0.02 E	-0.01 E	-0.01 E	-0.04 E
2020					-0.03 E
2021					-0.03 E

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WHAT'S NEW

Financial Update

On April 24, 2019, Midatech Pharma announced financial results for 2018. The company generated total gross revenue of £1.94 million, which included both collaboration income and grant revenue. R&D expenses in 2018 were £9.4 million compared to £8.3 million in 2017. The increase was primarily due to higher activity for both the MTD201 and MTX110 programs with both commencing key first-in-human studies in 2018. Administrative costs for 2018 were £4.4 million compared to £4.3 million in 2017. The increase was primarily due to loan redemption penalties and other costs associated with repaying the loan agreement with MidCap. Net loss from continuing operations was -£10.4 million. The loss from discontinued operations (which consists of the loss from the Midatech US business that was sold in Nov. 2018) was £4.7 million.

Midatech exited 2018 with approximately £2.3 million in cash and cash equivalents and a tax credit receivable of £2.0 million. In January 2019, Midatech announced a strategic licensing deal with Chinese Medical Systems (CMS) that included an equity investment. The license agreement grants CMS the exclusive rights to Midatech's clinical and preclinical assets (MTD201, MTX110 [subject to consent from Novartis], MTX102, MTR103, MTD119) in mainland China, Hong Kong, Macau, and Taiwan. In exchange, Midatech will receive a manufacturing margin in the low double digits for products it supplies to CMS and is also eligible to receive regulatory milestone payments, sales-based milestone payments, and a low double-digit royalty rate (MTX110 will have a net single digit royalty since Midatech must pay Novartis a royalty). In addition, CMS may also identify further product opportunities where Midatech would perform the initial development and then transfer the compound to CMS for further development. If those products go on to be approved, CMS would own the rights in the same territories with Midatech retaining the rights in the rest of the world.

Along with the license agreement, CMS entered into an agreement to purchase 207,792,206 Units at 3.85 pence per Unit, with each Unit comprising one common share of stock and one warrant to purchase a common share of stock at 50 pence per warrant. The net proceeds from this equity investment were approximately £7.4 million.

On February 26, 2019, the company announced that a total of £13.4 million in gross proceeds (£12.5 million net) were raised through the investment from CMS along with a private placement and open offer, all at the same terms. In Jan. 2019 the company announced the receipt of €1.5 million in the form of a loan from the Basque regional government to support the manufacturing facility in Bilbao, Spain and in Mar. 2019 announced it received notification from the Spanish government for a loan in the amount of €6.6 million for the same project. The money will go toward the commercial scale-up of MTD201. Provisions of the loan include Midatech providing a €2.6 million guarantee, which will likely come from bank financing. We anticipate that the company now has sufficient capital to fund operations through the first quarter of 2020.

Following the most recent financing, Midatech has 409,399,613 common shares outstanding that trade on the London stock exchange, with CMS owning approximately 51% of the shares. The company also has American Depository Receipts (ADRs) that trade on the Nasdaq Capital Market. Each ADR represents twenty of the company's ordinary shares, following a ratio change in April 2019. When factoring in the approximately 4.5 million stock options and approximately 314 million warrants, the company currently has a fully diluted share count of approximately 728 million.

Business Update

Ready to Advance MTD201

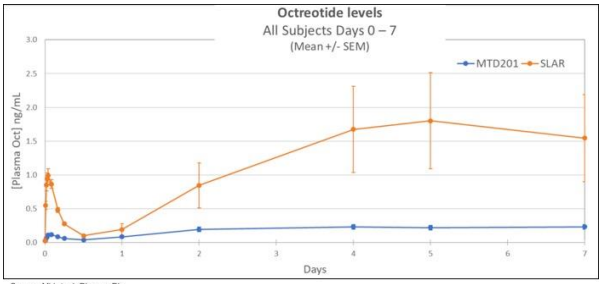
On January 25, 2019, Midatech announced it has received feedback from the FDA on the regulatory path forward for MTD201 (Q-Octreotide), the company's lead development program that utilizes the company's Q-Sphera™ sustained release technology. Previously in 2018, the company announced positive results from an exploratory first-in-human study of MTD201 (discussed below). In regards to the next step for MTD201, the FDA indicated that a single dose pharmacodynamic study in healthy volunteers would not be sufficient to support a new drug application (NDA). Thus, the company will need to perform either a multi dose study in healthy volunteers or a study in patients. In addition, the company will need to determine whether to establish equivalence between MTD201 and Sandostatin® LAR® (SLAR), the market leader in this $2 billion market, or whether to develop MTD201 as a differentiated product with an improved clinical profile. While a final decision has yet to be made, we anticipate that Midatech will choose to develop MTD201 as a differentiated product (see potential advantages of MTD201

compared to SLAR below). Regardless, the company is planning to initiate the next clinical trial in the second half of 2019 and submit for marketing authorization in 2021.

Positive Interim Data for MTD201

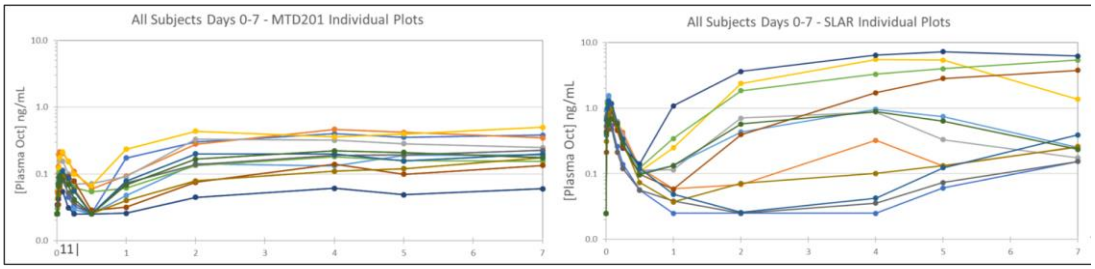
Earlier in 2018, Midatech announced positive interim results from a proof-of-concept study for MTD201. This first in-human, double blind, randomized, parallel group study enrolled 24 healthy volunteers and was designed to compare the sustained release profile between MTD201 and SLAR both pharmacokinetically (PK data on octreotide levels in the blood) and pharmacodynamically (PD data on growth hormone biomarker levels).

Results showed that MTD201 produced a favorable clinical profile and represents a potentially better product compared to Novartis' SLAR. The following figure shows average plasma octreotide levels for the subjects administered SLAR and MTD201. Interestingly, MTD201 has a smooth uptake and trajectory with almost no initial "burst" phase or dose dumping, while SLAR has poorly controlled bimodal release kinetics characterized by two peaks over the first 7 days before the product settle down, as shown in the following figure.



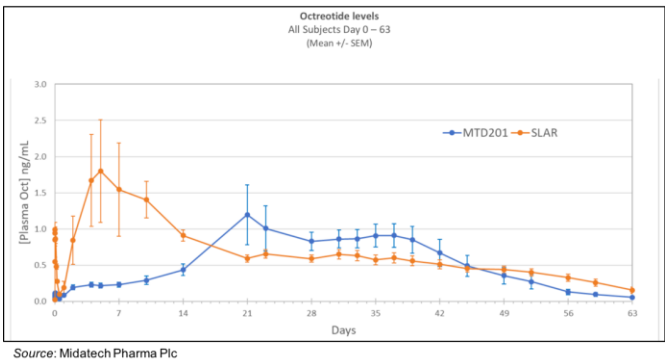
Source: Midatech Pharma Plc

The large error bars evident for the SLAR data shows the high variability of plasma octreotide release, which is in stark contrast to the very small error bars for the MTD201 data. This is exemplified in the following graphs that shows plasma octreotide levels for each individual subject. Following the initial burst phase, plasma octreotide levels in those administered SLAR vary by up to 100-fold. The graphs for each subject administered MTD201 are consistent, tightly grouped, and linear, which is in stark contrast to the unpredictable and variable graphs for those administered SLAR.



Source: Midatech Pharma Plc

The following figure shows the average level of plasma octreotide over 63 days for those administered MTD201 and SLAR. The plasma level of octreotide for those administered MTD201 steadily rises, settles at a plateau for the duration of the treatment period, then slowly tapers off, while the plasma level of octreotide peaks at approximately day 1, again at day 5, and then tapers off for those administered SLAR.



Source: Midatech Pharma Plc

These differences in plasma octreotide level between those administered MTD201 and SLAR translates into differences in the clinical outcome of growth hormone reduction, the pathology afflicting acromegaly patients. As part of the trial, healthy volunteers were given growth hormone releasing hormone (GRHR) and the % reduction in growth hormone (GH) level was recorded following administration of MTD201 or SLAR. The following table shows that MTD201 resulted in at least comparable normalization of GH levels and perhaps even a greater reduction as judged by the area under the curve (AUC) and Cmax.

Surrogate Efficacy Marker = Inhibition of GH release after GHRH Challenge

GH Endpoint at DAY 28	Treatment	Mean % Reduction from Baseline
Overall GH Response (Reduction) (AUC, h.ng/mL)	MTD201	28.6%
	Sandostatin LAR	26.4%
Peak GH Response (Reduction) (Cmax, ng/mL)	MTD201	30.4%
	Sandostatin LAR	17.8%

GHRH - growth hormone releasing hormone
GH - growth hormone
AUC - the area under the response curve
Cmax - the peak rise in growth hormone

Source: Midatech Pharma Plc

Additional features in which MTD201 may be superior to SLAR include:

1) A faster reconstitution time (10 min for MTD201 vs. 40 min for SLAR);
2) Additional time to use the product (up to two hours post reconstitution for MTD201 vs. needing to use immediately post reconstitution for SLAR);
3) Potential for longer dosing interval (6-8 weeks for MTD201 vs. 4 weeks for SLAR)
4) Potential for higher dose (up to 45 mg for MTD201 vs. up to 30 mg for SLAR)
5) Subcutaneous dosing (compared to intramuscular dosing for SLAR)
6) The ability to use a smaller gauge needle (21G needle used to administer MTD201 vs. 19G needle used to administer SLAR, although sometimes an 18G needle must be used due to blockages of 19G needles)

The last point above was exemplified by the fact that compared to SLAR, those administered MTD201 had much lower rates of pain at injection site (8% vs. 25%) and injection site tenderness (8% vs. 83%).

Q-Sphera™ Overview

The Q-Sphera™ platform was designed to address several problems associated with microencapsulation and polymer-depot based drug delivery. The high energy reactor-based emulsion processes such as those used to manufacture SLAR require a long duration (4-6 weeks), a large infrastructure, and are more wasteful in that they produce large quantities of unusable particles (i.e., either too large or too small). In addition, these emulsion processes use large volumes of unfavorable organic solvents (such as ethyl acetate and dichloromethane). Particles produced from these solvent solutions must be rigorously evaporated and washed to remove residual traces of solvent. The proprietary 'printer' approach MTP takes is unique in that it 'prints' the microspheres at several million spheres per second, uses non-toxic solvents easily removed via extraction, requires limited infrastructure, and a decreased manufacturing time.

The key advantage that the Q-Sphera™ approach offers is product monodispersity and homogeneity. Very tight particle size distributions can be produced, which increases the usable product yield and leads to an improved clinical profile and injectability characteristics compared to traditional manufacturing methods. For example, the Q-

Sphera™ platform results in products with the lack of a burst phase, lower variability, and reduced injection site pain (as seen in the results from the MTD201 proof-of-concept study) through the use of smaller gauge needles allowed by the homogeneous particle sizes. The end result of the Q-Sphera™ process is a formulation that produces consistent and reproducible drug concentrations in the body within very narrow limits.

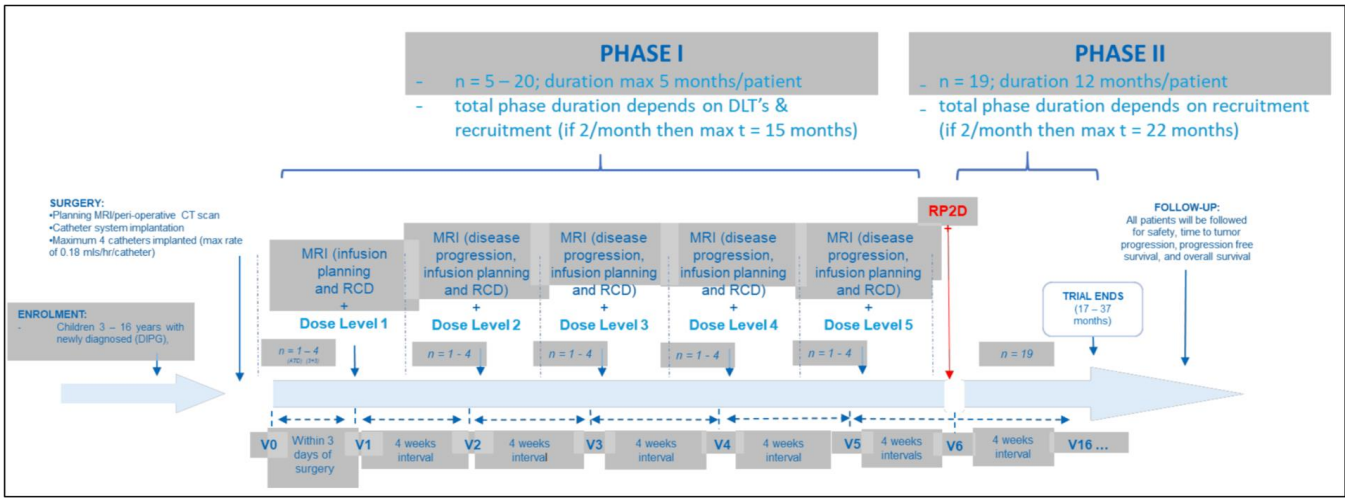
In summary, the Q-Sphera™ platform has the potential to improve numerous currently available therapies through:

- The formulation technology, which gives full control over particle size and release kinetics resulting in demonstrable clinical benefits;
- The manufacturing technology, which gives faster, simpler, less toxic, higher yield processes resulting in sustainable and efficient manufacturing;
- Multiple differentiating characteristics, including longer interval dosing, higher doses of drug, and subcutaneous administration, all of which result in clear competitive advantages;
- IP protection that extends beyond 2030

MTX110 Study Continues

In 2018, Midatech announced that dosing had commenced in the study of MTX110 for the treatment of diffuse intrinsic pontine glioma (DIPG), 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 trial is a combined Phase 1 and 2 study that will enroll up to approximately 40 patients, depending on various factors, particularly on how well the drug is tolerated in Phase 1. The company has added two additional dose escalations, in addition to the originally planned five doses, as there have been no serious adverse events reported thus far and MTX110 has been well tolerated. The Phase 2 portion of the trial will enroll 19 patients, with a primary outcome of one-year survival. The study will be positive if 12/19 patients survive for at least one year. We anticipate topline data from the efficacy portion of the study in 2020.



Source: Midatech Pharma Plc

The active component of 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 MidaSolve 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.

Panobinostat does not cross the blood-brain barrier effectively when given orally, 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. This occurs through convection-enhanced delivery (CED), 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.

Sale of Midatech Pharma US Inc. Completed

On November 1, 2018, Midatech announced that the proposed sale of Midatech Pharma US Inc., which runs the company's U.S. commercial operations, was completed for an upfront payment of $13 million and the potential for up to $6 million in additional consideration based on net sales of certain Midatech US products in 2018 and 2019. Upon completion of the sale, Midatech repaid the outstanding balance of the loan from MidCap Financial of $7.0 million plus prepayment costs and other fees, thus the company received approximately $4.5 million in net proceeds. The divestiture of the company's U.S. commercial operations was undertaken to allow all resources to be utilized for the advancement of the company's lead development products.

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 MidaSolve nanosaccharide inclusion (NI) for local delivery), in addition to its own in-house manufacturing for all of their products, help differentiate it from other biotechnology companies and the potential quick path to market for MTD201 and MTX110 could deliver significant revenues beginning in just a few years. We view the sale of the commercial group in the U.S. as a smart move by management such that resources can be fully focused on advancing the pipeline candidates forward to market as quickly as possible.

Due to the recent financing and the ratio change for the ADRs, we have made significant changes to our model. Following the financing, Midatech now has approximately 409.4 million shares outstanding (or 20.5 million ADRs), and our current valuation is now $10.00. However, we view the shares as de-risked now that the company is on more solid financial footing and has sufficient capital to advance the lead candidates along in clinical testing.

PROJECTED FINANCIALS

Midatech Plc
Income Statement

Midatech Pharma Plc (in millions of £)	2018 A	1H A	2H A	2019 E	2020 E	2021 E
MTX110 - DIPG Glioma	£0.0	£0.0	£0.0	£0.0	£0.0	£0.0
MTD201 - Acromegaly	£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	£1.9	£0.5	£0.5	£1.0	£1.0	£1.0
Total Revenues	**£1.9**	**£0.5**	**£0.5**	**£1.0**	**£1.0**	**£1.0**
Research & Development	£9.4	£4.8	£4.8	£9.6	£10.0	£12.0
Distribution Costs, Sales and Marketing	£0.0	£0.0	£0.0	£0.0	£0.0	£0.1
Administrative Costs	£4.4	£2.2	£2.2	£4.4	£4.5	£4.7
Impariment of Intangible Assets	£0.0	£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	-£11.8	-£6.5	-£6.5	-£13.0	-£13.5	-£15.8
Non-Operating Expenses (Net)	-£0.6	£0.0	£0.0	£0.0	£0.0	£0.0
Pre-Tax Income	-£12.4	-£6.5	-£6.5	-£13.0	-£13.5	-£15.8
Income Taxes Paid	-£2.0	-£0.2	-£0.2	-£0.4	-£0.5	-£0.5
Net Income	**-£10.4**	**-£6.3**	**-£6.3**	**-£12.6**	**-£13.0**	**-£15.3**
Loss from Disontinued Operations	-£4.66	£0.0	£0.0	£0.0	£0.0	£0.0
Total Income	-£15.0	-£6.3	-£6.3	-£12.6	-£13.0	-£15.3
Exchange Gain/Losses	-£2.7	£0.0	£0.0	£0.0	£0.0	£0.0
Total Comprehensive Gain/Loss	**-£17.7**	**-£6.3**	**-£6.3**	**-£12.6**	**-£13.0**	**-£15.3**
Net Loss per Share	**-£0.17**	**-£0.03**	**-£0.02**	**-£0.04**	**-£0.03**	**-£0.03**
YOY Growth	-	-	-	-	-	-
Basic Shares Outstanding	61.1	230.0	410.0	320.0	500.0	600.0

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

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