

Midatech Pharma Plc

(MTP-NASDAQ)

MTP: Positive Interim Results for MTD201 Proof-of-Concept Study...

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 \$5.50 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 (09/07/18) **\$0.76**
Valuation **\$5.50**

OUTLOOK

On August 31, 2018, Midatech Pharma Plc (MTP) announced positive interim results for the company's proof-of-concept study for MTD201 and the Q-Sphera technology. Results show that MTD201 produces an effective sustained-release octreotide profile that is comparable to Sandostatin® LAR® (SLAR), including an average 25% suppression of growth hormone levels. In addition, there was a much lower occurrence of pain at injection site (8% vs. 25%) and injection site tenderness (8% vs. 83%) for MTD201 compared to SLAR. That data, along with the fact that MTD201 has no unwanted initial burst release, a simpler and quicker reconstitution process, fewer reconstitution errors and wastage, and fewer needle blockages, means that MTD201 may be an improved product, not just an equivalent product. The company will be meeting with regulators in preparation for a follow-up trial.

SUMMARY DATA

52-Week High **\$2.30**
52-Week Low **\$0.50**
One-Year Return (%) **-65.69**
Beta **1.25**
Average Daily Volume (sh) **51,988**

Shares Outstanding (mil) **31**
Market Capitalization (\$mil) **\$23**
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 **-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	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2017	1.5 A	1.9 A	2.1 A	2.1 A	7.6 A
2018	2.2 E	2.2 E	2.3 E	2.3 E	9.0 E
2019					10.7 E
2020					10.8 E

Earnings per share

(In £)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2017	-0.09 A	-0.10 A	-0.06 A	-0.07 A	-0.31 A
2018	-0.07 E	-0.07 E	-0.06 E	-0.07 E	-0.26 E
2019					-0.21 E
2020					-0.24 E

WHAT'S NEW

Business Update

Midatech Pharma Plc (MTP) is a specialty pharmaceutical company with three novel drug delivery technologies that improve bio-distribution and bio-delivery of drugs. The technologies are designed to enable the targeted delivery, sustained release, or solubilized local delivery of existing therapeutic drugs.

The Q-Sphera next-generation sustained release (SR) technology platform, with numerous and distinct advantages over traditional polymer microsphere production, utilizes precisely and consistently manufactured monodispersed micro particles such that active drug compounds are released into the body in a tightly controlled and predictable manner over an extended period of time (e.g., weeks to months)

The gold nanoparticle (GNP) technology platform is based on GNP drug conjugates, which at 2 nm are among the smallest particles in biomedical use. They are composed of a core of gold atoms surrounded by a layer of carbohydrates and linkers for attachment of small molecules (e.g., chemotherapeutics, peptides, etc.) and targeting agents. The small size and multi-valency arrangement around the gold core underpin the ability to improve biodistribution and thus safety and efficacy of existing drugs.

The Nano Inclusion (NI) technology is utilized for potent small molecule chemotherapeutics that have minimal solubility at biological pH, which limits them to oral administration. When reformulated with the NI technology, the complexed molecules solubilize such that parenteral routes of administration can be employed. This enables local administration directly into the tumor.

Positive Interim Data for MTD201

On August 31, 2018, Midatech Pharma Plc (MTP) [announced](#) positive interim results from a proof-of-concept study for the company's lead development product MTD201 (Q-octreotide), a sustained release product of octreotide that utilizes the company's Q-Sphera sustained release technology.

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 Sandostatin® LAR® (SLAR) both pharmacokinetically (PK data on octreotide levels in the blood) and pharmacodynamically (PD data on growth hormone biomarker levels).

Results showed that MTD201 produces a safe and effective sustained-release profile of octreotide that is similar to SLAR, which included a similar suppression of growth hormone levels by an average of 25%. Importantly, MTD201 exhibited a number of attributes that potentially make it an improved product, including no burst release of octreotide upon administration, lower variability, much lower rates of pain at injection site (8% vs. 25%) and injection site tenderness (8% vs. 83%), a simpler and quicker reconstitution process, fewer reconstitution errors and wastage, and fewer needle blockages even with a much smaller needle than SLAR.

The company is planning to meet with regulators to get opinion and feedback on the next clinical trial, which could include testing for equivalence of MTD201 to SLAR or perhaps as a differentiated improved product. We anticipate learning more about the potential for a superiority study in the next few months.

Q-Sphera Overview

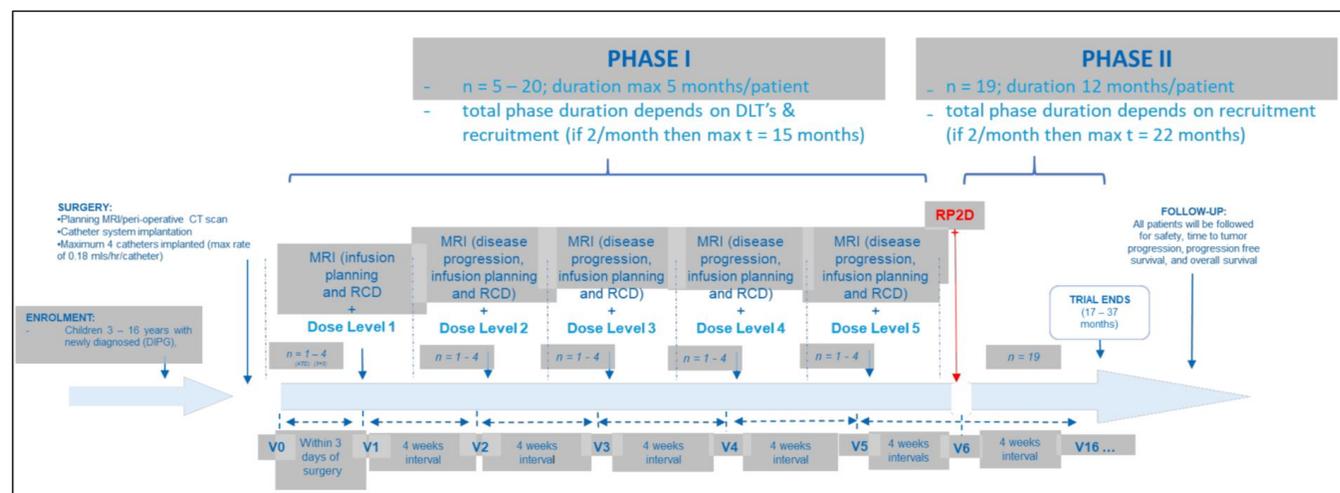
The Q-Sphera platform was designed to address several problems associated with microencapsulation and polymer-depot based drug delivery. The emulsion processes such as those used to manufacture SLAR are more wasteful in that they produce large quantities of unusable particles (i.e., either too large 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 washed to remove residual traces of solvent. The approach MTP takes is unusual in that it does not rely on solvent evaporation. Instead, a solvent extraction method is utilized. 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 improved injectability characteristics compared to traditional manufacturing methods. For example, injection site pain can be reduced (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.

MTX110 Study Underway

On May 25, 2018, Midatech announced that dosing has 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 approximately 40 patients. The Phase 1 safety portion of the study is expected to report data in the second half of 2019 while the Phase 2 efficacy portion of the study is expected to report data in 2020. An outline of the trial is shown below.



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 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.

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.

To date, MTX110 has been used on a compassionate use basis to treat five DIPG 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.

Gelclair® Trial Underway

On June 8, 2018, Midatech announced that patient enrollment is now underway in the Phase IV clinical trial of Gelclair® in patient undergoing stem cell transplant therapy. The trial is taking place at Dana-Farber/Brigham and Women's Cancer Center and is designed to study the effect of Gelclair® on various aspects of oral mucositis (OM). OM is a common side effect of chemotherapy and/or radiotherapy that results in inflammatory ulcerating of the oral mucosa. This leads to pain, bleeding, weight loss, and an increased risk of infections (Bellm *et al.*, 2000). Approximately 40-99% of patients who receive high-dose chemotherapy and/or total body irradiation before hematological stem cell transplantation develop OM, with severe OM (grade 3 or 4) occurring in up to 67% of stem

cell transplant recipients ([Wardley et al., 2000](#)). In the U.S., approximately 200 centers perform roughly 40,000 stem cell transplants each year.

The trial is a blinded, randomized study to test the efficacy and tolerability of Gelclair® and the ideal timing of initiation of therapy for treating OM in allogeneic stem cell transplant patients conditioned with high-dose chemotherapy. Gelclair® is currently the leading gel barrier prescription product prescribed for OM in patients receiving various radiation and chemotherapy cancer treatments. The results of this study should help guide healthcare decisions regarding the use of Gelclair® in stem cell transplant recipients who experience OM. We anticipate enrollment in the trial finishing in the second half of 2018.

Financial Update

On July 23, 2018, Midatech [announced](#) that Midatech Pharma US Inc. has signed a co-promotion agreement with Bausch Health Companies Inc. in which Midatech will become the exclusive promoter of NeutraSal®, Bausch Health's supersaturated calcium prescription product that is intended for the treatment of dry mouth due to certain cancer treatments. Midatech Pharma US Inc. will promote NeutraSal® with the company's specialty oncology sales force. Terms of the agreement were not disclosed, however Midatech will receive a percentage of NeutraSal® net sales from prescriptions generated at U.S. based oncology practices.

On July 25, 2018, Midatech [provided](#) a trading update that included expected financial results for the first six months of 2018. The company expects gross product revenues (before product returns, discounts, rebates, and other incentives) of approximately £5.8 million, which represents a 16% increase from the £5.0 million in gross product revenue for the first six months of 2017. Sales in the first half of 2017 represented approximately 56% of full year revenues, and we are expecting a similar split for 2018. We are pleased to see the company continuing to steadily grow product revenues and look forward to the release of full financial results in September 2018.

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.

The interim results from the proof-of-concept study of MTD201 are really encouraging and the potential for the product to be an improvement over SLAR is unexpected and increases the potential for the Q-Sphera platform. We look forward to learning additional details about the potential for MTD201 as a better product compared to SLAR in the coming months. 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. Based on the potential for MTD201, we have increased potential peak sales, which has increased our valuation to \$5.50 per share. The stock is trading a substantial discount to our current valuation and we believe as more investors become aware of Midatech's potential the stock price will increase to be more in-line with our valuation.

PROJECTED FINANCIALS

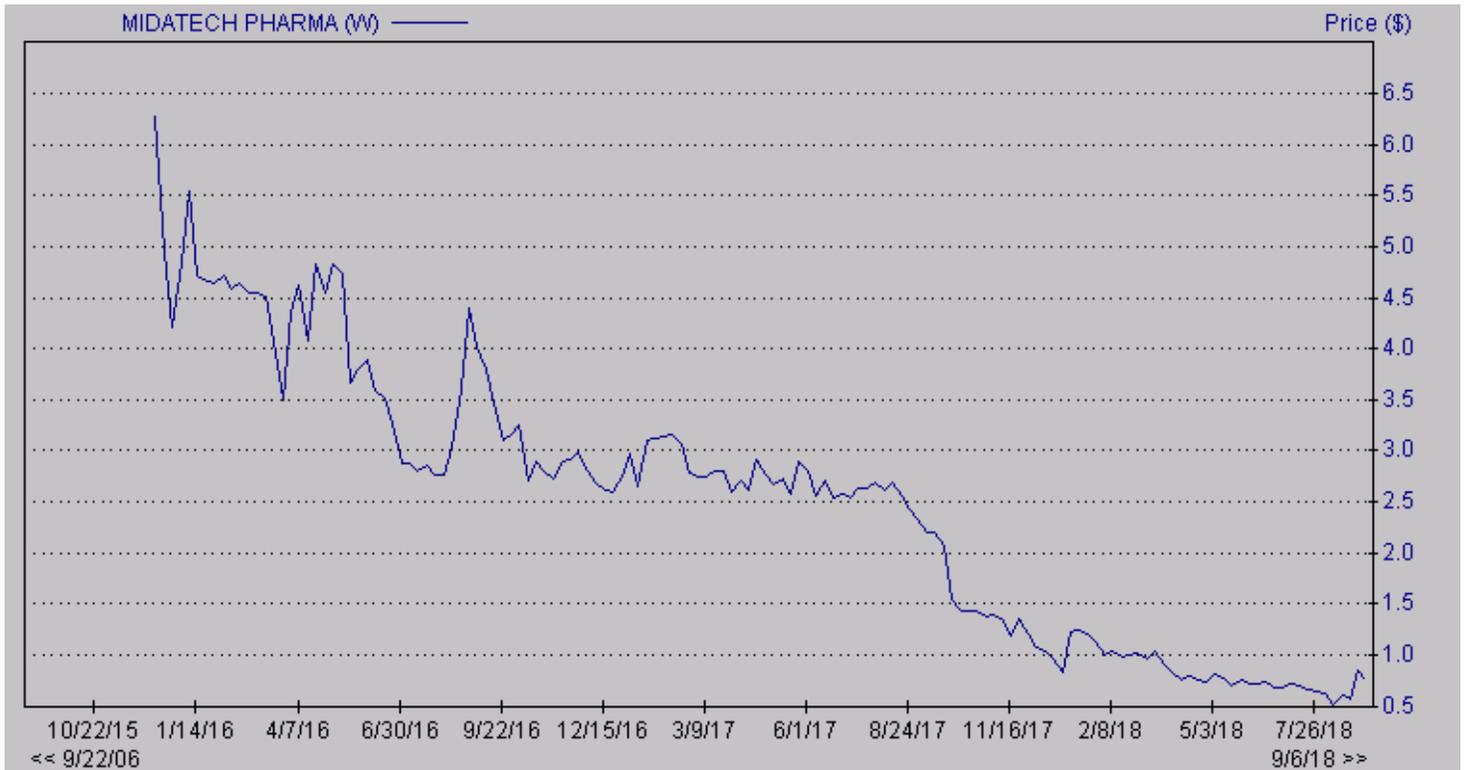
Midatech Plc Income Statement

Midatech Pharma Plc (in millions of £)	2017 A	1H E	2H E	2018 E	2019 E	2020 E
Midatech Pharma US	£6.8	£4.0	£4.2	£8.2	£10.2	£10.3
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	£0.8	£0.4	£0.4	£0.8	£0.5	£0.5
Total Revenues	£7.6	£4.4	£4.6	£9.0	£10.7	£10.8
Cost of Sales	£0.9	£0.6	£0.7	£1.3	£1.5	£1.5
Research & Development	£10.2	£6.0	£6.0	£12.0	£13.0	£14.0
Distribution Costs, Sales and Marketing	£9.4	£4.6	£4.7	£9.3	£10.0	£11.0
Administrative Costs	£3.1	£2.0	£2.1	£4.1	£4.2	£4.4
Impairment of Intangible Assets	£1.5	£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	-£17.6	-£8.8	-£8.9	-£17.7	-£18.0	-£20.1
Non-Operating Expenses (Net)	£0.25	-£0.1	-£0.1	-£0.20	-£0.1	-£0.1
Pre-Tax Income	-£17.3	-£8.9	-£9.0	-£17.9	-£18.1	-£20.2
Income Taxes Paid	-£1.3	-£0.6	-£0.6	-£1.2	-£1.0	-£1.0
Net Income	-£16.1	-£8.2	-£8.4	-£16.6	-£17.1	-£19.2
<i>Net Margin</i>	-	-	-	-	-	-
Exchange Gain/Losses	-£1.2	£0.0	£0.0	£0.0	£0.00	£0.00
Total Comprehensive Gain/Loss	-£17.3	-£8.2	-£8.4	-£16.6	-£17.1	-£19.2
Net Loss per Share	-£0.31	-£0.14	-£0.13	-£0.26	-£0.21	-£0.23
<i>YOY Growth</i>	-	-	-	-	-	-
Basic Shares Outstanding	51.3	61.0	65.0	63.0	80.0	85.0

Source: Zacks Investment Research, Inc.

David Bautz, PhD

HISTORICAL STOCK PRICE



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