Zacks Small-Cap Research

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David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Midatech Pharma Plc

MTP – Nasdaq

MTP: Receives Approval to Initiate First In Human Trial of Q-Octreotide (MTD201); Four Year Loan Agreement with MidCap Financial…

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 (01/12/2018)	$1.25
Valuation	**$6.50**

OUTLOOK

Midatech Pharma Plc (MTP) recently announced that Polish regulators have given approval to conduct the first in-human study of Q-Octreotide (MTD201), a sustained release version of octreotide that could potentially enter a roughly $2 billion market in 2020. Interim data from the study should be available in mid-2018, with final data anticipated in 2H18.

In addition, the company also recently entered into a four-year secured loan agreement with MidCap Financial for up to $15 million of funding. Midatech received the initial tranche of $7 million, with the issuance of additional funds being dependent upon clinical development milestones for MTD201 and MTX110.

SUMMARY DATA

52-Week High	**$3.22**
52-Week Low	**$0.84**
One-Year Return (%)	**-55.42**
Beta	**-0.41**
Average Daily Volume (sh)	**351,604**
Shares Outstanding (mil)	**N/A**
Market Capitalization ($mil)	**$39**
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 #Lin Estimate	**N/A**
P/E using #Lin 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)
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

	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

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WHAT'S NEW

Business Update

Set to Initiate First Clinical Trial for Q-Octreotide

On January 9, 2018, Midatech Pharma Plc (MTP) announced that Polish regulators have given approval to initiate the company's first in-human clinical trial of Q-Octreotide (MTD201). We anticipate the company will begin dosing subjects soon. Q-Octreotide is the sustained release (SR) version of octreotide, an octapeptide that mimics naturally occurring somatostatin. Octreotide is an existing, immediate- and sustained- release injection product used to decrease the production of growth hormone in people suffering from acromegaly and for the treatment of neuroendocrine (hormone secreting) tumors (NET). It is sold by Novartis under the brand name Sandostatin® and the sustained release version Sandostatin® LAR®.

Acromegaly is considered an orphan indication as it only affects approximately 20,000 individuals in the U.S., with approximately 1,000 new cases diagnosed each year (Holdaway *et al*., 1999). In 2016, Novartis reported approximately $1.6 billion in revenues for Sandostatin® LAR®. In addition to Sandostatin®, Somatuline® is sold by Ipsen, which generated €538 million in 2016 revenues, and Somavert® is sold by Pfizer, which generated $232 million in 2016 revenue (EvaluatePharma). If Midatech was able to achieve only 5% of the acromegaly market (which totals approximately $2.2 billion), that would represent an approximately $100 million opportunity.

Q-Sphera: Sustained Release Technology

Q-Octreotide is based on the company's SR polymer microsphere technology (Q-Sphera). The Q-Sphera platform was designed to address several problems associated with the microencapsulation and polymer-depot based drug delivery. 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. Very tight particle size distributions can be produced, which increases the usable product yield. Emulsion processes, such as those used to manufacture Sandostatin® LAR®, are more wasteful in that they produce large quantities of unusable particles (i.e., either too large or too small). Additionally, 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 Q-Sphera approach to forming particles by "desolvation" is applicable to many polymer types. The polymers Midatech uses most frequently are linear poly-esters of lactic (PLA) and glycolic acids (i.e., polylactide-co-glycolide, [PLGA]) that are insoluble and unstable in water due to simple hydrolysis. Each of these can be processed into any shape or size and they are soluble in a wide range of solvents. In addition, the rate of drug release can be easily controlled through altering the physico-chemical properties of the polymer(s). In the body, hydrolysis is the dominant mechanism for the controlled degradation of the polymer microparticles. This is also the reason that the microspheres cannot be provided as a pre-mixed, ready-to-use suspension product. They must be stored dry, (i.e., freeze-dried) to remove traces of water.

Clinical Trial Plan for Q-Octreotide

Midatech will be performing a two-phase clinical trial: an exploratory phase in 24 healthy volunteers, followed by a confirmatory phase in an additional up to 76 subjects, giving an expected total of 100 subjects for the study. The company is hoping to show interchangeability with Sandostatin® LAR® both pharmacokinetically and pharmacodynamically, thus potentially offering patients an alternative treatment for NETs, carcinoid syndrome, and acromegaly. We anticipate initial data in mid-2018 and final results in the second half of 2018. Assuming positive clinical results, the company plans to file for approval under the 505(b)(2) pathway, potentially as early as 2020.

Phase IV Study of Gelclair® Underway

On December 20, 2017, Midatech announced the initiation of a Phase IV study of Gelclair® at Dana-Farber/Brigham and Women's Cancer Center to study its effect 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 allogenic 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 January 2, 2018, Midatech announced it entered into 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. This financing will help further extend Midatech's cash runway into 2019, and importantly the company has sufficient capital to get through important inflection points in 2018 including the data from the Q-Octreotide study and initiation of the MTX100 study.

Valuation

We recently initiated coverage of Midatech in Nov. 2017 and are encouraged by the recent news showing that the company is continuing to execute on its business plan. The company'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. Our valuation for Midatech is $6.50 per share, and with the stock trading at a significant discount to our valuation we believe investors should take a closer look at the company, particularly ahead of important data read outs later in 2018.

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	£3.5	£6.5	£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	£0.5	£0.9	£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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