Stock Data	
Share Price:	10.00p
Market Cap:	£9.85m
Shares in issue:	98.49m
52 week high/low:	51.95p – 9.50p

Company Profile	
Sector:	Biotechnology
Ticker:	MTPH
Exchanges:	AIM, Nasdaq[1]

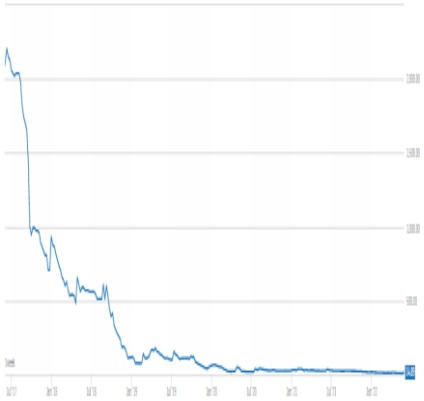
[1]Note: Ratio 1 ADS : 5 Ord. Shares

Activities

Midatech Pharma plc ('Midatech', 'MTPH', 'the Group') is a developer of therapeutic platform technologies and also focuses on the Research and Development ('R&D') of medicines for the treatment of rare cancers and other lethal diseases through in-house as well as partnered programmes while seeking to license its technologies.

www.midatechpharma.com/

5-year share price performance chart



Source: LSE

Past performance is not an indication of future performance.

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Midatech Pharma plc

Midatech confirmed last Wednesday that it had been granted Fast Track designation by the US Food and Drug Administration ('FDA'), for the treatment of recurrent glioblastoma multiforme ('rGBM') through its MTX110 development programme. This important milestone follows clearance of its Investigational New Drug ('IND') application for a Phase 1 study of the drug, a Panobinostat complex to be administered by convection enhanced delivery ('CED') in patients, on 13 December 2021. The Group initiated preparations for a signal-finding study to commence before the end of H1 2022 that could point the way to a new treatment paradigm for this intractable brain cancer. First data could be available as early as Q4 2022. With the Group's monthly cash burn having been reduced to c.£0.5 million, and having successfully raised £10 million (gross) through a UK equity placing on 29 June 2021, its Board expects to have sufficient cash resources to fund operations into the first quarter of 2023. Sustaining its 'multiple shots on goal' strategy, a pipeline of nine different programmes targeting improvements in bio-delivery/biodistribution of existing drugs offers significant potential for positive news over this period. Along with expectation of moving its two indications for MTX110 forward, there is also realistic potential for delivery of senior partnership agreements both for its ground-breaking early-stage work in therapeutic monoclonal antibodies ('mAb') and its later-stage Q-Sphera small molecule programmes (MTD211 & MTD219), suggesting the remainder of 2022 is likely to become heavier in news flow for the Group.

FDA Fast Track Designation – What does it mean?

A drug that receives Fast Track designation from the FDA becomes eligible for some or all of the following:

- More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met
- Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application ('BLA') or New Drug Application ('NDA') for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA

Fast Track designation must be requested by the drug company. The request can be initiated at any time during the drug development process. The FDA will review the request and make a decision within sixty days based on whether the drug fills an unmet medical need in a serious condition. Once a drug receives Fast Track designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

MTX110 – Delivering therapeutic doses direct to the target tumour

rGBM is the most common and aggressive form of intractable brain cancer in adults, usually occurring in the white matter of the cerebrum. Current treatments include radiation, surgical resection and chemotherapy although, in almost all cases, tumours

recur. Survival with standard of care treatment ranges from approximately 13 months in unmethylated O6-methylguanine-DNA methyltransferase ('MGMT') patients to approximately 30 months in highly methylated MGMT patients.

In October 2020, Midatech announced results from the Phase 1 study (MTX110) for Diffuse Intrinsic Pons Glioma ('DIPG'), an aggressive childhood brainstem tumour with a dismal prognosis, that was undertaken at University of California San Francisco ('UCSF'). These demonstrated good safety and tolerability at the proposed Phase 2 dose and unexpectedly good survival data (with a median at 26 months compared with a median of just 10 months for a historical cohort of over 300 patient cases). Given the low incidence of this condition relative to rGBM, which has a much larger potential market (2 to 3 diagnoses per c.100,000 population each year, suggesting a value in the range of US$3 billion to US$5 billion) with limited other treatment options, however, Midatech has chosen to prioritise rGBM in order to attract potential funding partners. That said, recognising that both therapeutic areas are targeted using similar panobinostat infusion via patient-friendly 'pump and catheter' system, the Board considers prospective partners might wish to assume responsibility for both indications in tandem.

Employing MidaSolve™ technology, MTX110 solubilises panobinostat, a histone deacetylase ('HDAC') inhibitor currently used in the treatment of multiple myeloma. In a liquid formulation as MTX110, panobinostat can be delivered directly to a patient's tumour in high doses under constant pressure via a CED system, as a means to bypass the blood-brain barrier while permitting high drug concentrations (estimated to be some 100,000-times that achieved through oral solution) along with broader drug distribution in/around the tumour and simultaneously minimising systemic toxicity and other side effects. Panobinostat has already demonstrated high potency against patient-derived tumour cells in *in vitro* and *in vivo* models. The primary objective of the Phase 1 study will be to assess the safety and tolerability of MTX110 in patients with rGBM. The study is expected to include two clinical centres in the US, recruitment for which is expected to get underway imminently.

Secura Bio still seeking to terminate Midatech's Panobinostat license

Complexities surrounding MTX110's Panobinostat license that Midatech originally secured from Secura Bio Inc. ('Secura Bio) have already been discussed at length. The Group last received correspondence from Secura Bio's counsel in summer 2021, seeking (once again) to terminate their agreement while also demanding non-exclusive license to Midatech's own IP. Whether this most recent additional demand is down to the fact that Secura Bio recognises the value Midatech is creating through its research is unclear, but having previously attempted to force the Group's withdrawal in June 2020, this appears to simply repeat an exercise that the Board considers to be entirely without merit. Although opportunistic in that it is based on slightly different grounds, their claims appear to be no more realistic than the first. Meanwhile discussions with external partners for potential co-development of MTX110 continue, although not surprisingly they have been hindered by COVID-19. At best, Midatech considers the distraction caused by Secura Bio to be unfortunate and has repeatedly invited Secura Bio to close its action. Contemplating a 'worst case' scenario for prudence, however, a terminated license would mean that while the Group retains safe harbour to work with the molecule in R&D, it would not be able to commercialise it until the composition of matter patent expires in 2026; this legal dispute is therefore not likely to impact the priority GBM product given that it is not expected to be sufficiently advanced for commercialisation by that time in any case.

Outlook for further news updates/potential revenue generation – A busier second half in prospect

The second half of 2022 looks set to be a relatively busy period for Midatech, both on the potentially significant news front and in terms of opening doors for additional revenue generation. Realistically, a potential list of prospective releases could possibly include any of all of the following:

- A near-term announcement of first patient, first visit to commence the Phase I rGBM trial. This is likely to take place at Brain Tumor Centre at Duke University in North Carolina, given that the centre treats as many as 800 individuals each year with the condition and so has access to a large quorum of potentially eligible patients.
- The ending of the Phase I DIPG trial (at Columbia University), where recruitment of suitable patients has been complicated by the extreme rarity of the condition, with the final patient (of a total of 10 individuals) is expected to be admitted for treatment mid-to-late June 2022.
- Subject to the above, first patient for the Phase II DIPG trial for which, given that there are no other approved treatments, could possibly be recognised as a Registration Study by the FDA, permitting commercialisation without the need to complete a time consuming and expensive Phase III trial, albeit remaining subject to the ongoing monitoring of those

who are prescribed the drug for any possible side effects.

- Application for MTX110's European Orphan Drug status which, having already been awarded in the US, would likely accelerate review process etc. undertaken by the European Medicines Evaluation Agency ('EMEA').
- IND award for MTD211whose API (Q-brexpiprazole profile) is for the treatment of schizophrenia/major depressive disorder ('MDD'). The opportunity here is significant, given its demonstrated capability for 20% drug loading that enables up to 90-days sustained delivery. It outperforms drug suspension approaches used for other accelerated approval pathways developments, which instead rely on the poor solubility and slow dissolution of drug particles at the injection site. With formulation optimisation ongoing based on human PK steady state simulations of rabbit data, an IND could ideally position Midatech to identify a licensee to support development. Being an internal program, this could even be opened up as an auction amongst interested parties for the rights.
- Conversion of one of the two Q-Sphera technology R&D collaborations ongoing with Janssen Pharmaceutica NV into a licence/tech transfer agreement.
- Recognising the major potential and broad sector interest in the modified release mAb programme, updates regarding additional formulations using its Q-Sphera platform.

Midatech Pharma plc – Development Pipeline

ID	API	Therapeutic Area	Administration	Formula-tion	Preclinical	Phase I	Phase II	Partner Status
Q-Sphera:								
MTD211	brexpiprazole	Schizophrenia / MDD	LA injectable					-
MTD219	tacrolimus	Transplant rejection	LA injectable					-
MTX213	undisclosed	undisclosed	LA injectable					Collaboration
MTX214	undisclosed	undisclosed	LA injectable					Collaboration
MTX216	undisclosed	undisclosed	LA injectable					Collaboration
MidaSolve:								
MTX110	panobinostat	DIPG	Infusion via CED					-
MTX110	panobinostat	GBM	Infusion via CED					-
MTX110	panobinostat	Medulloblastoma	Direct to tumour					-
MidaCore:								
MTX114	methotrexate	Psoriasis	Topical					-

Source: Midatech, Investor Presentation, September 2021

TPI retains its target valuation for Midatech, equivalent to 99p/share

TPI last updated its valuation for Midatech following two significant news announcements released in June 2021, along with continuing progress across its development pipeline. Back then, an exceptional level of international interest had been expressed following the Group's release of 17 June 2021, detailing breakthrough data that indicated protein loading up to 15% w/w with it retaining functional integrity throughout encapsulation and release, as demonstrated in an in vitro antigen binding assay. Given that the industry has long sought long-acting formulations for monoclonal antibodies in a market for which the top 10 drugs account for c.US$75 billion in annual sales, TPI apportioned additional prudent value to this early-stage discovery which might be expected to multiply once a senior development partner has been formally identified. On 29 June 2021, Midatech raised £10m new equity funding, which the Board considers will continue to provide it with a runway out to Q1 2023. TPI retains its sum-of-parts valuation across the Group's different internal and external programmes at £97.5 million which, based on the present number of shares in issue, produces a target price to 99p/share.

(Please note that TPI's valuation is based on financial modelling and there is no guarantee that such a valuation will ever be realised, therefore please do not base investment decisions on this valuation alone.)

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