

Stock Data

Share Price:	21.2p
Market Cap:	£20.9m
Shares in issue:	98.47m
52 week high/low:	52.0p – 18.2p

Company Profile

Sector:	Biotechnology
Ticker:	MTPH
Exchanges:	AIM, Nasdaq ¹

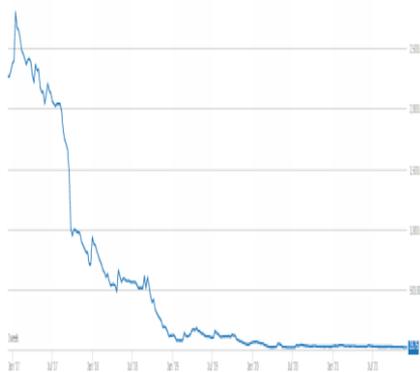
¹Note: Ratio 1 ADS: 5 Ord. Shares

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](https://www.lse.com/)

Past performance is not an indication of future performance.

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Midatech Pharma plc

Midatech has announced its Investigational New Drug ('IND') application for a Phase 1 study of MTX110, a panobinostat complex to be administered by convection enhanced delivery ('CED') in patients with recurrent glioblastoma multiforme ('rGBM'), has been cleared by the US FDA. The Group has initiated preparations for a signal-finding study to commence in 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 Q3/Q4 2022. With the Group's monthly cash burn now 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/bio-distribution 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 groundbreaking early-stage work in therapeutic monoclonal antibody ('mAb') and its later-stage Q-Sphera small molecule programmes (MTD211 & MTD219), suggesting the New Year is likely to be heavy in exciting news flow for the Group.

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 were 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' (or CED) 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 and to begin recruiting H1 2022.

Secura Bio still seeking to terminate Midatech's Panobinostat license

Complexities surrounding MTX110's Panobinostat license that Midatech originally secured from Secura Bio Inc. have already been discussed at length. The Group last received correspondence from the Company'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 latest 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 their 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.

Midatech Pharma plc – Development Pipeline

ID	API	Therapeutic Area	Administration	Formulation	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, November 2021

Timelines for further news updates and potential revenue generation

2022 looks to be a relatively busy period for Midatech, both on the news front and in terms of opening doors for new revenue generation. MTD211's (Schizophrenia/Mild Depressive Disorder ('MDD')) Q-brexiprazole profile, for example, appears to be almost ideal, achieving a 20% drug loading to enable up to 90-days sustained delivery; as such it outperforms drug suspension approach used for other accelerated approval pathways developments, which relies 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, it now appears to be ideally positioned to identify a licensee to move it forward. An announcement on this basis might be anticipated in the coming months. Being an internal program, this will be opened up as an auction amongst interested parties for the rights. The two PoC developments delivered to the Group's partner also opens the relatively near-term opportunity to engage through a tech transfer agreement. Of course, should the partner not wish to proceed, the program comes to an end which, although considered relatively unlikely, is the reason the Board keeps a balance between partnered and internal programmes.

Given the major potential and sector interest in the modified release mAb programme and Midatech's intention to identify additional formulations using its Q-Sphera platform, further updates and potential partnership development news might also be expected on this in coming months, along with progress for MTX110 as its clinical trials get underway in H1 2022, followed by first data in H2 2022.

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

TPI has updated its valuation for Midatech following two significant news announcements released in June 2021, along with continuing progress across its development pipeline. An exceptional level of international interest has 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 has now apportioned prudent value to this early-stage discovery which might be expected to multiply once a senior development partner has been formally identified. Later that same month, Midatech raised £10m new equity funding, which the Board considers now provides it with a runway out to Q1 2023. The result has been for TPI to increase its sum-of-parts valuation across the Group's different internal and external programmes to £97.5 million (compared to £65.7m previously in analysis published on 10 September 2020), although factoring in the increased number of shares in issue has reduced TPI's target price to 99p/share (compared to 104.2p previously).

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