

Stock Data

Share Price:	10.66p
Market Cap:	£10.50m
Shares in issue:	98.49m
52 week high/low:	28.80p – 7.40p

Company Profile

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

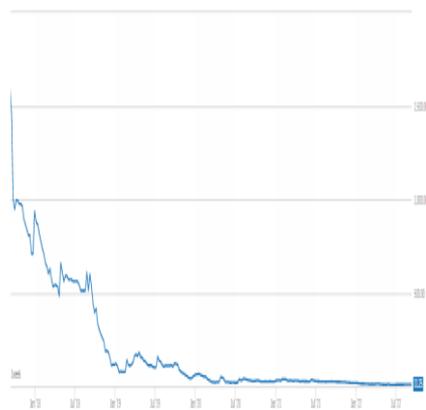
¹Note: Ratio 1 ADS : 5 Ord. Shares

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 unaudited interim results for the six months ended 30 June 2022. Very much in line with expectations, total revenue for the six months was £0.47m (H1 2021: £0.40m), coming entirely from R&D collaborations with Janssen in the absence of grant income. Cash burn of £3.63m (H1 2021: £3.34m) left the Group with a balance of £6.42m, which the Board considers sufficient to fund operations into Q1 2023 while also noting that it is now actively considering options for extending its runway. Significant news accompanying today's release includes both a new opportunity to leverage the Group's Q-Sphera technology through the targeted, intratumoral delivery of metabolic modulating agents and the impending start of the MXT110 trial in recurrent glioblastoma multiforme ('rGBM'). 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 updates over the coming months. 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 and Q1 2023 are likely to deliver heavier news flow for the Group.

Financial highlights for the six months to 30 June 2022

- Total revenue in H1 2022 was £0.47m (H1 2021: £0.40m). Total revenue represents income from R&D collaborations;
- Research and development costs in H1 2022 increased by 20% to £2.41m (H1 2021: £2.01m) as a result of increased costs associated with MTX110 as the Group prepares for its Phase I study in rGBM;
- Administrative expenses increased 12% in H1 2022 to £1.85m (H1 2021: £1.64m) primarily due to increased legal and professional expenses;
- Net cash used in operating activities (after changes in working capital) in H1 2022 was £3.54m, compared with £3.11m in H1 2021.
- The cash balance on 30 June 2022 was £6.42m.

Product & business development during the six months to 30 June 2022

Midatech concentrated on two specific product development issues during H1 2022: (i) Building on the Q-protein discovery work completed in 2021 and, (ii) Preparing MTX110 for a Phase I study in rGBM. During the period it also expanded its business development efforts through outreach and partnering conferences.

Q-Sphera Pipeline: Q-Sphera technology employs proprietary 3-D printing techniques to encapsulate drugs in polymer-based bioresorbable microspheres which may be injected to form depots in the body which release drugs over predictable, sustained periods from one week to several months. Progress reported for the Q-Sphera pipeline in 1H 2022 includes:

- Proteins (including mAb) formulation - There are no approved long-acting injectable formulations of biologic products (such as mAbs or other high molecular weight proteins) primarily because they are delicate and easily de-natured in manufacture. In 2021 Midatech demonstrated the successful encapsulation of an exemplar mAb and

most importantly, preservation of its functional and structural integrity and antigen binding *in vitro*.

In 1H 2022 Midatech continued to expand and develop its in-house capabilities around the encapsulation of high molecular weight proteins. The Group is presently developing methods for the successful encapsulation of bispecific T cell engager molecules ('BiTEs'), which are a type of fusion protein created by linking the targeting regions of two antibodies that are designed to harness the power of the immune system to treat cancer. Similar work is being undertaken with Antibody Drug Conjugates ('ADCs'), which also have shown utility in oncology settings.

- **MTX213 and MTX223** - In 1H 2022, the Group signed R&D collaboration agreements with Janssen to focus on maximizing drug loading and optimizing *in vitro* duration of release for two large molecules it had nominated. To date, the first work package has been completed and the second is currently underway.

Highlighting recent findings, management also considers there to be important opportunities to leverage the Group's Q-Sphera technology through targeted, intratumoral delivery of metabolic modulating agents, in combination with standard-of-care treatments. Such an approach could potentially delay (or help to overcome) resistance to standard-of-care treatment and so increase patient survival while also improving efficacy and lowering systemic side effects. Although promising, in-house experiments carried out in intratumoral delivery to date remain at an early stage and will require more time, effort and investment before validation. Recognising the longer-term opportunity this presents, however, Midatech has recently filed a patent designed to protect this research and development.

MTX110 – This novel formulation of panobinostat that is administered through convection enhanced delivery, is in clinical development for intractable brain cancers including GBM and Diffuse Intrinsic Pontine Glioma ('DIPG'). Both being incurable conditions marked by short survival rates and universal recurrence, GBM is the most common and devastating primary malignant brain tumour in adults encompassing 14.3% of all primary brain and central nervous system neoplasms. With an incidence of approximately 3.2 per 100,000 population in the USA, approximately 12,300 people in the USA are diagnosed with GBM per annum. Having already achieved Orphan Drug status in the US, following the submission of a similar application to the European Medicines Agency ('EMA'), on 21 June 2022 Midatech's development programme of MTX110 for the treatment of glioma was granted Orphan Medicinal Product designation by the agency.

Building on the *in vivo* data that Midatech presented at the 2020 annual meeting of The Society of Neuro-Oncology, which demonstrated the efficacy of MTX110 against two GBM cell lines in an ectopic tumour model and subsequent *in vitro* which demonstrated the potency, at therapeutic concentrations, of MTX110 against a further four patient-derived GBM cell, Midatech began planning a Phase I pilot study in rGBM patients. All preparations for the study have been completed and management expects to enrol the first patient at the beginning of the fourth quarter at the Preston Robert Tisch Brain Tumor Center, Duke University.

The ongoing second Phase I study in DIPG at Columbia University is in the process of recruiting the last of 10 patients. Panobinostat has already demonstrated high potency against DIPG tumour cells in *in vitro* and *in vivo* models, and in a key study was found to be the most promising of 83 anticancer agents tested in 14 patient-derived DIPG cell lines (*Grasso et al, 2015. Nature Medicine 21(6), 555-559*).

Outlook for further news updates/potential revenue generation – A busier six months to come

The coming six months 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 list of potential news releases could possibly include any or all of the following:

- A near-term announcement of first patient, first visit to commence the Phase I rGBM trial. It has been decided that this will take place at the Brain Tumor Center at Duke University in North Carolina, given that as many as 800 individuals with the condition are treated there each year 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) now expected to be admitted for treatment later this month or early next.

- 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.
- IND award for MTD211 whose API (Q-brexipiprazole 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	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, September 2021](#)

Anticipating more significant news flow in coming months

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. At this time TPI retains its sum-of-parts valuation across the Group's different internal and external programmes at £97.5 million in anticipation of more significant news flow confirming the potential of its development pipeline over the coming six or so months. This could open a number of options for the Board to consider extending its present cash runway through different routes, including fundraising and/or partnering the Group's assets and technologies.

(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. Also please note that past performance, future performance and forecasts are not reliable indicators of future results.)

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