Midatech Pharma

Pharma and biotech

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Pipeline delivery key to future outlook

Midatech's FY21 results continued to reflect financial prudence (following the March 2020 business realignment), with normalised operating loss improving to £7m (£10.7m in FY20) despite a much broader R&D pipeline. Clinical asset MTX110 (MidaSolve platform), already in Phase I for orphan DIPG and medulloblastoma brain cancers, is expected to commence a Phase I study in mid-2022 for recurrent glioblastoma, an opportunity more than 30 times the size of the other two combined. We believe visibility from the Q-Sphera pipeline will improve investor confidence. With the current cash balance (£10.1m at the end of FY21) only sufficient to fund operations to early 2023, we anticipate that potential partnerships and/or licensing deals will de-risk the near-term outlook.

MTX110 moves closer to the clinic in GBM

Following the December 2021 FDA clearance, MTX110 is expected to commence a Phase I study in recurrent glioblastoma (rGBM) in mid-2022. These dose-escalation studies (enrolling 10–12 patients with GBM) will take place across two sites in the United States with early progression-free survival data expected by Q422. We assume that following this pivot, clinical efforts with diffuse intrinsic pontine glioma (DIPG) will transition to a more 'post-marketing' endeavour. rGBM is a materially larger opportunity ($3–5bn market potential globally versus $100m for DIPG), although we note that time to market is likely longer/more expensive given the requirement for larger, randomised studies. However, positive data should open up opportunities to partner MTX110 for rGBM (and ultimately GBM).

Greater visibility will underpin value of Q-Sphera pipeline

The Q-Sphera platform is Midatech's core technology focus and currently encompasses two in-house and two partnered assets (in collaboration with Janssen). While the FY21 report broadly discussed this pipeline, we believe a clearer roadmap and better visibility in terms of progress is required to assuage the current cautious market sentiment. In particular, traction with the in-house assets MTD211 (long-acting brexpiprazole) and/or MTD219 (long-acting tacrolimus) would be important, as will any upcoming plans for further asset development under the platform.

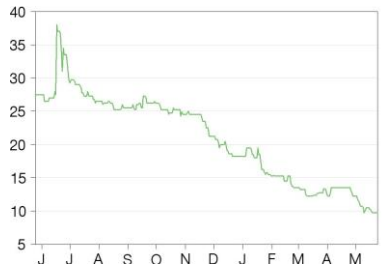
Historical financials

Year end	Revenue (£m)	PBT (£m)	EPS (p)	DPS (p)	P/E (x)	Yield (%)
12/18	1.94	(11.8)	(339)	0.0	N/A	N/A
12/19	0.67	(10.9)	(50)	0.0	N/A	N/A
12/20	0.34	(11.1)	(23)	0.0	N/A	N/A
12/21	0.58	(6.1)	(6.8)	0.0	N/A	N/A

Source: Midatech Pharma company filings. Note: PBT and EPS are normalised.

Price	9.8p
Market cap	£10m

Share price graph



Share details

Code	MTPH
Listing	AIM
Shares in issue	98.5m
Net cash at end December 2021	£10.1m

Business description

Midatech Pharma is platform-based drug delivery specialist founded in 2000 and listed on AIM in 2014. Its three technology platforms, Q-Sphera (for sustained release of drugs), MidaSolve (nano inclusion for local delivery) and MidaCore (gold nanoparticles for targeted delivery), are designed to re-engineer and reformulate existing therapeutic drugs with the aim of improving biodistribution and delivery. The realigned focus is on the Q-Sphera development pipeline and the clinical asset MTX110 (for brain cancer).

Bull

- Scalable technology platforms with a broad product pipeline.
- First-in-class potential in aggressive brain cancers.
- Early success in encapsulating a mAb.

Bear

- Challenges in finding partners/out-licensing opportunities.
- Requirement for additional funding and potential equity dilution risk.
- Earlier-stage product out-licensing strategy may limit upside potential of partnership deals.

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Midatech's pipeline update

Midatech's FY21 results summarised the developmental status of its asset pipeline, reiterating its 'multiple shots on goal' strategy as a lever for future growth. As a refresher, the company specialises in improving the biodelivery and biodistribution of existing medicines by leveraging its three technology platforms: Q-Sphera, MidaSolve and MidaCore. Following a strategic review in early 2020, Midatech has pivoted its focus from a narrow, targeted pipeline to a broader, albeit early-stage asset portfolio (both in house and partnered), with the intention of partnering following proof-of-concept (PoC). The goal is multifold: to diversify pipeline risk, generate multiple partnering opportunities to monetise Midatech's technologies and alleviate the financing obligations on the company. Legacy asset MTX110 (solubilised panobinostat) is the company's only clinical-stage programme and is targeting the high unmet need in the aggressive brain cancers space. Q-sphera (long-acting formulations of existing drugs) is the near-term focus and where we expect the bulk of near-term R&D activities to be focused, although clinical data will come from MTX110 (MidaSolve) first. The platform encompasses four assets, including two in-house (MTD211 and MTD219) and two partnered assets (MTD213 and MTD223) (Exhibit 1).

Exhibit 1: Midatech's therapeutic's pipeline

ID	Technology	API	Therapeutic Area	Administration	Formulation	Pre-clinical	Phase I	Phase II	Partner
MTX110	MidaSolve	Panobinostat	Recurrent Glioblastoma Multiforme	Direct to tumour via CED	X	X	X		
MTX110	MidaSolve	Panobinostat	Paediatric brain cancer (DIPG)	Direct to tumour via CED	X	X	X		
MTX110	MidaSolve	Panobinostat	Medulloblastoma	Direct to tumour via CED	X	X	X		
MTD211	Q-Sphera	Brexpiprazole	Schizophrenia, MDD	Long acting Injectable	X	X			
MTD219	Q-Sphera	Tacrolimus	Anti- transplant rejection	Long acting Injectable	X	X			
MTX213	Q-Sphera	Undisclosed	Undisclosed	Undisclosed	X				Janssen Pharmaceutica
MTX223	Q-Sphera	Undisclosed	Undisclosed	Undisclosed	X				Janssen Pharmaceutica
MTX114	MidaCore	Methotrexate	Mild to moderate psoriasis	Topical	X				

Source: Midatech

MTX110 to commence Phase I studies in GBM in mid-2022

In December 2021, Midatech received FDA clearance to commence a clinical trial for its most clinically advanced programme, MTX110 in recurrent GBM (rGBM). MTX110 uses the company's proprietary MidaSolve technology to solubilise the chemotherapy drug Panobinostat, which is then delivered through a convection-enhanced delivery system directly to the site of the tumour. The planned Phase I pilot study is expected to commence by mid-2022 across two clinical centres in the US (Duke University and MD Anderson Cancer Center). The primary objectives will be to assess safety and tolerability in patients with rGBM (dose-escalation study estimated to recruit between 10 and 12 patients), but the study will also track preliminary efficacy signals such as PFS. Midatech expects to release preliminary data from the study by Q422. We expect this to be a key upcoming catalyst for the company.

We note that MTX110's primary focus thus far has been on the ultra-rare childhood brain cancer DIPG, for which Midatech had received the orphan drug designation from the FDA in October 2019. In October 2020, the company reported exceptionally positive interim survival data from a Phase I study – median overall survival of 26.06 months versus 10 months following standard-of-care radiation therapy in historical cohorts. This pivot is therefore surprising, although the larger market potential ($3–5bn versus $100m for DIPG) and possible greater attractiveness to future partners may have been a factor in driving this decision. This strategy does hold some merit in our view

given the significantly larger patient population and lack of treatment options despite significant R&D efforts – only three drugs are currently approved for the treatment of GBM: Temozolomide (chemotherapy), bevacizumab (anti-VEGF monoclonal antibody; not approved in Europe) and Nitrosourea/gliadel wafer (chemotherapy). On the flip side, however, we also anticipate materially higher competition in the space, with a likely longer time to the market and the need for more rigorous clinical trials (with higher associated expenses). In addition, the company may lose the market exclusivity benefit which came along with the orphan drug designation in DIPG as well as favourable regulatory policies around paediatric conditions. For the longer term, we are encouraged by Midatech's plans to develop MTX110 as a combination therapy for brain cancers given that therapeutic challenges surrounding brain cancers can, at least partly, be attributed to their molecular heterogeneity, which can arguably be targeted using a combination treatment regime.

Greater traction with Q-Sphera could trigger stock re-rating

Q-Sphera, Midatech's patented sustained-release drug delivery platform, is the key near-term focus for the company. The Q-Sphera pipeline currently comprises four distinct assets – two in-house small molecule assets MTD211 (long-acting brexpiprazole) and/or MTD219 (long-acting tacrolimus) and two large-molecule assets under development as part of an R&D collaboration with Janssen. Midatech delivered PoC in MTD211 in H221 and has been actively seeking out-licensing opportunities. We highlight that brexpiprazole is the only marketed antipsychotic that does not have an approved long-acting version and comes with a sizeable market opportunity (see our initiation note for more detail). Management had indicated recent interest in MTD211 in the US market and we await further updates on possible partnering successes. Positive newsflow on this front could potentially trigger a re-rating of the stock, in our view.

For the two partnered assets, Midatech is currently working on maximising the drug loading (drug as a proportion of the total microsphere mass) and optimising the dissolution profile (in vitro duration of drug depot release) of Janssen's exemplar mAbs. This follows the early success the company has had in encapsulating a biologic using the Q-Sphera technology. While the current collaboration terms involve reimbursing Midatech at a multiple of its direct development costs (3–4x), the goal is to optimise the partnership by entering into a technology transfer/out-licensing agreement for an income stream consisting of upfront and milestone payments, as well as royalties on sales. We expect the company to continue to adopt this dual strategy in the near future. For 2022, Midatech has indicated plans to add up to two additional candidates to its internal Q-Sphera pipeline as well as targeting R&D collaborations specifically in the areas of peptides and proteins.

FY21 financials

Midatech's FY21 financial performance was in line with the recent 'post-restructuring' trend. Revenue increased to £0.58m (£0.34m in FY20 including £0.16m in a Spanish government grant), primarily attributed to the company's R&D collaboration with Janssen. With the extension of the collaboration agreement in early 2022, we expect the company to report higher revenues for FY22 (c £2m as guided by management). Normalised operating loss for the year improved to £7m (£10.7m in FY20) due to the removal of R&D costs associated with legacy asset MTD201. The H221 operating loss of £3.9m was broadly in line with the H121 figure of £3.1m, reflecting a more sustainable financial matrix, post restructuring. R&D costs, which make up the bulk of operating expenses (c 60%) went down from £6.1m to £4.7m due to £1.8m lower clinical development costs on legacy asset MTD201, partially offset by higher expenses on ongoing R&D. With MTX110 set to enter the clinic and plans to expand the Q-Sphera pipeline, we expect a steady ramp-up in R&D expenses in the next few years.

Following the £10m equity raise in July 2021, Midatech ended the year with a cash balance of £10.1m, which management expects to be sufficient to fund operations into Q123. With MTX110 data expected by Q422 and in anticipation of better visibility on the Q-Sphera portfolio, we expect

the company to focus on seeking non-dilutive options (partnerships/licensing) to fund further development in favour of further equity raises.

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