Biodexa Pharmaceuticals

Pivoting out of a challenging FY22

Biodexa has reported its FY22 preliminary results and revised business strategy for the medium term. Funding challenges and slower traction than anticipated with the clinical pipeline during the period compelled the company to undertake cost-reduction initiatives (terminating all internal Q-Sphera development programs) and pivot its business model from a drug delivery company to a therapeutics play in March 2023 (along with a name change, AIM delisting and share consolidation). Looking ahead, we expect the strategic focus to be on delivering proof-of-concept (PoC) for its development pipeline, in particular for lead Phase I asset MTX110 (in aggressive brain cancers). The $6m (£5m) equity raise in February provides a runway to Q423, past the crucial interim safety and efficacy data from the Phase I recurrent glioblastoma (rGBM) study anticipated in Q323. Potential licensing deals on the back of positive MTX110 data should provide operational headroom and de-risk the near-term outlook.

MTX110 Phase I rGBM readout a key priority for FY23

MTX110 is in Phase I development for three rare brain cancers, rGBM, diffuse intrinsic pontine glioma (DIPG) and medulloblastoma, and we see the biggest opportunity in rGBM given its sizeable market potential and unmet need. Patient recruitment to the Phase I study (MAGIC-G1 study) began in November 2022 (two cohorts with minimum four patients each; cohort 1 – MTX110 monotherapy, cohort 2 – MTX110 + lomustine) and we expect interim data from cohort 1 to be announced in Q323. The brain cancer space has a high risk-reward trade-off and MTX110 data, if positive, may pave the way for significant outlicensing deals, which should help de-risk the company's operations in the near term.

Quest for new assets to bolster the R&D pipeline

Biodexa's new R&D strategy centres on developing drug candidates synergistic with its proprietary technology platforms. The focus will be on oncology and rara/orphan indications with the aim to deliver clinical PoC before seeking partners for further development. In March 2023, Biodexa announced a new preclinical program, MTD217, targeting leptomeningeal disease, a secondary metastatic cancer of the central nervous system (CNS) that has a poor prognosis. The drug will be developed using Biodexa's MidaSolve platform. The company has also announced that it will be seeking to acquire/in-license another pipeline candidate in FY23. We expect the £5m in funds raised to be partially used for these initiatives but believe a more ambitious growth strategy would require a larger financing pool.

Historical financials

Year end	Revenue (£m)	PBT (£m)	EPS* (p)	DPS (p)	P/E (x)	Yield (%)
12/19	0.67	(10.9)	(997)	0.0	N/A	N/A
12/20	0.34	(11.1)	(1,036)	0.0	N/A	N/A
12/21	0.58	(6.1)	(136)	0.0	N/A	N/A
12/22	0.70	(8.5)	(155)	0.0	N/A	N/A

Source: Biodexa company filings. Note: PBT and EPS are normalized. *Adjusted for the 1:20 share consolidation announced in March 2023.

Price	US$0.23
Market cap	US$4m

Share price graph

Share details

Code	BDRX
Listing	Nasdaq
ADS in issue at April 2023	18.9m
Pro-forma net cash (end FY22 + February 2023 equity raise)	c £7.8m

Business description

Biodexa Pharmaceuticals is a clinical-stage biopharmaceutical company developing pipeline candidates with focus on oncology and rare and orphan indications. Lead candidate MTX110 is in Phase I clinical studies in aggressive rare/orphan brain cancer indications including recurrent glioblastoma, diffuse intrinsic midline glioma and medulloblastoma. The pre-clinical pipeline includes MTD217, targeting leptomeningeal disease, a secondary metastatic cancer of the central nervous system that has a poor prognosis.

Bull

- First-in-class potential in aggressive brain cancers with MTX110.
- Therapeutics portfolio supported by three enabling platforms.
- Upside from potential partnering for drug delivery platforms.

Bear

- Challenges in finding partners/out-licensing opportunities.
- Challenging macroeconomic environment making fund-raising difficult.
- Earlier-stage product out-licensing strategy may limit upside potential of partnership deals.

Analysts

Adam McCarter +44 (0)20 3077 5700

Jyoti Prakash, CFA +44 (0)20 3077 5700

healthcare@edisongroup.com

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FY22 results in line; FY23 to focus on cost optimization

Biodexa's FY22 financial performance was unsurprising and in line with the recent trend. Revenue increased 21% y-o-y to £0.7m (FY21: £0.58m) and, as with FY21, this was fully attributable to the company's R&D collaboration with Janssen. Biodexa had announced two R&D collaborations with Janssen (in January and March 2022), tasking the company to maximize drug loading and optimize the in vitro duration of the release for two of Janssen's experimental large molecules using Biodexa's Q-Sphera technology platform. While the first assignment has been completed, the second is ongoing. We expect this to deliver additional revenue inflows in FY23, albeit lower than FY22, in our view.

Reported operating loss for the year increased to £8.9m (£7m in FY21) driven by a 54% y-o-y rise in administrative expenses (£4.5m vs £3.0m in FY21) largely due to a £1.36m fee related to the proposed acquisition of Bioasis in December 2022 and a £0.4m provision against payment made and loan commitments to Bioasis. Being one off, we expect administrative expenses to normalize in FY22. R&D costs, which make up the bulk of operating expenses (53%, lower than the 61% in FY21) grew 10% y-o-y to £5.1m. This was primarily attributable to increased clinical costs related to MTX110 and investment in in-house R&D capabilities, partially offset by lower pre-clinical costs and portfolio rationalization. With recruitment ongoing in the Phase I rGBM study, R&D investments on the program will likely rise in FY23, although some of this increase should be offset by the discontinuation of the Q-Sphera internal programs.

Operating cash burn during the period was £7.1m and the company ended the year with a cash balance of £2.8m, which was bolstered by the £5m fund raise in February 2023. Management has guided that this pro-forma balance (£7.8m) will be sufficient to fund operations to end FY23 based on the current R&D pipeline and operational priorities. We expect cost optimization to be a key priority for Biodexa in FY23 to support extending the cash runway past the crucial MTX110 readouts (anticipated in Q323). In March 2023, Biodexa undertook a cost-management program (terminating all internal development with the exception of MTX110), which included headcount reduction. An associated one-time cost of £88,000 will be recognized in FY23. The company also plans on generating some cost savings by delisting from AIM and maintaining a single listing (ADS) on Nasdaq. We note that Biodexa recognized an impairment of £207k ($250k) in FY22 and created another £207k provision against possible future credit losses related to the $500k loan to Bioasis ($250k each in December 2022 and January 2023) as part of the original deal with the company.

Reinventing itself with a fresh strategy and new name

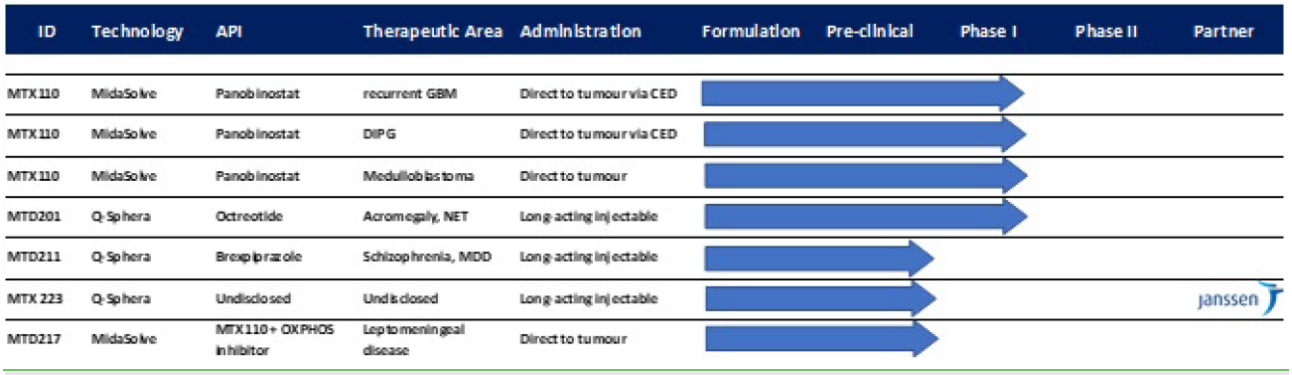
Biodexa's operational focus in FY22 centred on its drug-delivery platforms (Q-Sphera, MidaSolve and MidaCore) with the aim to develop a mix of in-house and partnered candidates (reformulation of existing drugs with improved safety, efficacy and usability). The core focus was on Q-Sphera and the company saw success with its two R&D collaborations with Janssen. However, delays in finding partners for the internal Q-Sphera pipeline (Q-brexpirazole and Q-tacrolimus) along with wider biotech funding constraints forced the company to reassess its business strategy and positioning.

After shareholders turned down its proposed merger with Bioasis (December 2022), Biodexa was successful in raising £5m ($6m) in February 2023 using a cashbox structure, which, although highly dilutive, allowed it to continue operations, effect its new business strategy (of being a therapeutics company with enabling drug-delivery technologies) and extend its cash runway to Q423. As part of the restructuring, Biodexa undertook a 1:20 share consolidation (March 2023) and subsequently delisted from the AIM market (April 2023), maintaining its ADS listing on Nasdaq.

Exhibit 1 presents Biodexa's current R&D pipeline. MTX110 is the company's only clinical-stage program, targeting the high unmet need in the aggressive brain cancer space. MTD217 is the

recently announced preclinical program, as highlighted previously. We note that the company's Q-sphera (long-acting formulations of existing drugs) internal development programs (MTD201 and MTD211) are available for partnering, but no active development work is ongoing on these.

Exhibit 1: Biodexa's therapeutics pipeline



Source: Biodexa Pharmaceuticals 6-K, April 2023

While we acknowledge Biodexa's strategic rationale for restructuring its business operations and repositioning itself (on the basis that therapeutics companies are more attractive to investors than drug-delivery players), we note the increased risk associated with a core therapeutic focus given the long lead times and sizeable upfront expenses. A narrower pipeline focus (in this case MTX110) also increases the business risk given that binary events often dictate outlooks.

Near-term focus on MTX110 in rGBM

We expect Biodexa's core focus in FY23 to be on advancing its clinical studies for MTX110, in particular for rGBM. Biodexa received FDA clearance to start Phase I clinical trials in rGBM in December 2022. MTX110 uses the company's MidaSolve technology to solubilize the chemotherapy drug Panobinostat, which is then delivered through a convection-enhanced delivery system directly to the site of the tumor. Patient recruitment to the Phase I pilot study (MAGIC-G1) began in November 2022. The study is an open-label, dose-escalation study, recruiting patients across two cohorts (minimum of four patients each), with one cohort receiving MTX110 as monotherapy and the other receiving MTX110 in combination with lomustine (a cytotoxic chemotherapy drug approved for patients with rGBM). The primary objectives will be to assess the feasibility and safety of intermittent infusions of MTX110 delivered through an implantable convection-enhanced delivery (CED) system, although the study will likely also track preliminary efficacy signals. The study will use the same single-catheter CED system used in the first Phase I study in DIPG, which reported encouraging headline data in October 2020. We also note that the FDA granted the fast-track designation to MTX110 in rGBM in June 2022.

In January 2023, Biodexa announced that the Data Safety Monitoring Board has recommended dose escalation from 60uM to 90uM (expected to be the target therapeutic dose for MTX110) following completion of one month of treatment for the first patient on the lower dose, which was well tolerated. The second patient in cohort one (who we understand was recruited towards the end of January 2023) will be administered this higher dose. Management has indicated that, depending on the safety signals from the higher dose, the study will need to recruit at least three more patients before progressing to the next cohort. If things go to plan, the company aims to announce interim data from cohort 1 in Q323. We view this event as the primary upcoming catalyst for Biodexa with the potential to trigger a strong share-price re-rating. Note that MTX110 is also being evaluated in an ongoing Phase I DIPG study, for which management has indicated that only one more patient is required for completion. Data from this study may also be announced in H223. In addition, MTX110 is also be evaluated as a treatment for medulloblastoma in a pilot study at the University of Texas.

Scouting for other attractive oncology targets

In addition to MTX110, Biodexa also announced a new pre-clinical program in March 2023, MTD217, targeting leptomeningeal disease, a secondary metastatic cancer of the CNS, with currently poor prognosis (average survival of 3–6 months). MTD217 is being designed to simultaneously target key metabolic pathways – glycolysis/Warburg effect and the oxidative phosphorylation (OXPHOS) pathway, used by cancer cells to generate energy for growth and proliferation. According to the company, under induced stress, cancer cells switch from glycolysis to the OXPHOS pathway for energy, so the inhibition of both should support broader utility and efficacy. While small-molecule drugs can be used to downregulate these pathways, usage has been restricted by off-target toxicity from systemic administration of these drugs. By solubilizing these drugs using the MidaSolve technology and directly delivering the therapeutics to the site of the cancer cells (simultaneously or sequentially), Biodexa is proposing a more effective (higher dose concentrations) and safer (limiting off-target toxicity) alternative to available treatments, for both primary and metastatic cancers. Biodexa is working on initiating preclinical studies (in collaboration with several large academic centers) with the aim to generate proof-of-concept data to support clinical progression. In addition, management has also indicated that it is seeking to acquire at least one other asset to in-license in FY23 in the oncology space, with a focus on rare or orphan indications. We expect Biodexa to focus on pre-clinical or very early clinical-stage candidates, given the level of investment required for more advanced assets.

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London | New York | Frankfurt
20 Red Lion Street
London, WC1R 4PS
United Kingdom