Trinity Delta

Mereo BioPharma

Update

H120 results and corporate review

12 October 2020

Mereo BioPharma is progressing the promising anti-TIGIT antibody, etigilimab, into Phase Ib/II trials for multiple solid tumour types in Q420 and intends to host an investor webinar focusing on this asset in a similar timeframe. Partnering discussions for setrusumab (osteogenesis imperfecta, OI), are ongoing with options sought to retain certain commercialisation rights. Clinical trials are underway again, with Phase II data for alvelestat in anti-alpha trypsin deficiency (AATD) is expected in H221. Financing options for acumapimod and leflutrozole are also being explored. Although its early stage means its contribution to our rNPV model is currently modest, success with etigilimab would be transformative for the company. Using conservative assumptions our current valuation is 101p/share or $5.06/ADS (fully diluted).

Year-end: December 31	2018	2019	2020E	2021E
Sales (£m)	0.0	0.0	0.0	0.0
Adj. PBT (£m)	(35.1)	(40.5)	(39.3)	(28.2)
Net Income (£m)	(32.0)	(34.8)	(143.5)	(26.7)
Adj.EPS (p)	(42.2)	(38.4)	(21.3)	(7.3)
Cash (£m)	27.5	16.3	34.8	11.9
EBITDA (£m)	(35.2)	(36.9)	(34.9)	(27.1)

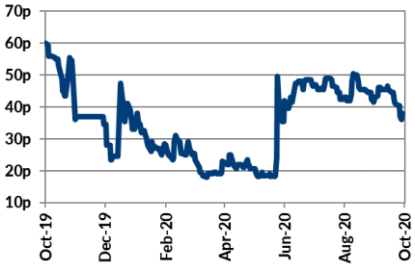
Source: Trinity Delta Note: Adjusted numbers exclude share-based payments and exceptionals.

- **TIGIT programme Phase Ib/II starts in Q420** Mereo Biopharma's H120 results were in line with expectations. Cash of £56.8m suggests development of the key programmes is funded through to early-2022. The main news is confirmation that etigilimab Phase Ib/II studies are set to start in Q420. This will initially recruit 75 to 100 patients with a variety of solid tumours and explore etigilimab's efficacy and safety in combination with an as yet unnamed PD-1 inhibitor. More detail is expected when the study initiates enrolment, with a management webcast planned. We view etigilimab as a potentially transformative programme for the company.

- **Partnering discussions are underway** Several assets are at, or approaching, partnering points, the most significant being setrusumab (OI). An appropriate partner is required ahead of starting the pivotal Phase III paediatric registration trial, with management seeking to retain commercialisation rights for certain geographies. Alvelestat (AATD) has restarted its Phase II study (recruitment was impacted by COVID-19) which is expected to deliver top-line results in H221. Navicixizumab (ovarian cancer) was partnered earlier this year, and funding options for acumapimod (AECOPD) and leflutrozole (male infertility) are being explored.

- **Valuation of 101p per share or $5.06 per ADS** Updating our rNPV model post-H120 report values Mereo Biopharma at £570m or $741m, equivalent to 101p/share or $5.06/ADS (fully diluted). With funding secured, and knowledgeable institutional investors on board, we believe share price appreciation will now be driven by clinical progress and demonstrable success in partnering assets. In our view, Mereo BioPharma is still largely underappreciated and, hence, undervalued.

Price (UK share) (US ADS)	38.0p $2.22
Market Cap	£128.7m $150.4m
Enterprise Value	£99.6m $112.4m
Shares in issue (shares) (ADS)	338.71m 67.74m
12-month range	13.0p-65.0p $0.69-$4.25
Free float	35.1%
Exchanges	AIM London NASDAQ
Sector	Healthcare
Company codes	MPH.L MREO
Corporate client	Yes



Company description

Mereo BioPharma develops and commercialises innovative therapeutics addressing oncology and rare diseases. These are acquired or licensed in at clinical stages from large pharmaceutical companies. The portfolio consists of six compounds that are progressing through late-stage clinical development.

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Mereo BioPharma: focussed on execution

Mereo BioPharma's now solid financial position allows management to focus on executing its development plans for its key programmes, notably its promising anti-TIGIT programme. Etigilimab is set to start a Phase Ib/II PD1 combination trial in a variety of solid tumour types during Q420. Although early stage, etigilimab is particularly exciting and, if successful, could transform Mereo's prospects. Meanwhile, the orphan and rare disease products, setrusumab, for osteogenesis imperfecta (OI or brittle bone disease), and alvelestat, for the treatment of alpha-1 antitrypsin deficiency (AATD), continue to progress. Partnering discussions are known to be underway, with attractive deals being clear value inflection points. Our valuation is £570m or $741m, equivalent to 101p/share or $5.06/ADS (fully diluted).

Cash of £56.8m means key development funded through to early-2022

Mereo BioPharma's H120 results were in line with expectations, with cash of £56.8m at June (vs £36.1m at end-H119) following the £11.8m raised as equity and debt in Q120 and the impressive £56m ($70m) equity raise in Q220. Management now has the resources to progress its development plans through to early-2022. The product pipeline consists of six later-stage clinical assets: two in oncology, two in rare diseases, and two earmarked for partnering (Exhibit 1). The portfolio is well diversified, with each of the product candidates employing a different mechanism of action and targeting a distinct indication. Our recent Outlook note (September 2020) provides a detailed company overview and analysis of the portfolio.

Exhibit 1: Mereo BioPharma pipeline summary

Product	Source	Indication (Target)	Status	Next steps
Etigilimab (OMP-313M32)	OncoMed	Solid tumours (+/- anti-PD1) (anti-TIGIT)	Phase Ia and one Ib completed	Additional Phase Ib, progress to Phase II; trial to start Q420
Setrusumab (BPS-804)	Novartis	Osteogenesis imperfecta [OI] (anti-Sclerostin)	Phase IIb completed, 12m follow on ongoing	Partnering and Phase III (paediatrics)
Alvelestat (MPH-966)	AstraZeneca	α1-antitrypsin deficiency (NE inhibitor)	Phase II proof-of-concept ongoing	Complete Phase II (data in H221)
Navicixizumab (OMP-305B83, NAVI)	OncoMed	Ovarian cancer (c paclitaxel) (anti-DLL4/VEGF bispecific)	Phase Ib ongoing	Partnered with OncXerna*
Acumapimod (BCT-197)	Novartis	Exacerbations in COPD (p38 MAPK inhibitor)	Phase III ready	Partnering
Leflutrozole (BGS-649)	Novartis	Testosterone deficiency [HH] (aromatase inhibitor)	Phase III ready	Partnering

Source: Mereo BioPharma, Trinity Delta Note: NE = neutrophil elastase; HH = Hypogonadotropic Hypogonadism, * formerly known as Oncologie

Etiligimab progress is, in our view, the key to unlocking value

Etigilimab, an anti-TIGIT antibody, is in our view the most promising programme. It targets the TIGIT (T-cell immunoreceptor with immunoglobulin and ITIM) domains, which is a particularly exciting area in immuno-oncology as it appears to stop T-cells from attacking tumour cells much like the PD-1 inhibitory protein. These are known as immune checkpoint receptors and their inhibitors (CPI), targeting checkpoints such as CTLA-4 (cytotoxic T lymphocyte-associated antigen 4) and PD-1 (programmed cell death 1) receptors, have transformed clinical

practice. However, a sizeable patient population fail to respond or relapse, and the search is on for new CPI targets that improve treatment outcomes. TIGIT is viewed by many as a next generation CPI, with extensive clinical programmes currently underway. There are ten TIGIT programmes known to be in clinical development, albeit four have only just entered Phase I.

Phase Ib/II study set to begin patient enrolment in Q420

Etigilimab showed promising results in a 23 patient Phase Ia open label dose escalation trial in locally advanced and metastatic solid tumours and a related 10 patient Phase Ib dose escalation study, in combination with nivolumab. No dose limiting toxicities were observed in either study. Management has confirmed that a Phase Ib/II study of etigilimab in combination with a PD-1 inhibitor is planned to start in Q420. This will involve 75 to 100 patients with a range of solid tumours, including a selection of less common types. We expect etigilimab will be progressed through proof-of-concept Phase II studies, with the data being pivotal in guiding the development strategy.

Setrusumab, an effective treatment option in a poorly served patient group

Setrusumab, for osteogenesis imperfecta (OI), is the most advanced programme in the rare disease portfolio. It has successfully completed a Phase IIb study (ASTEROID) and is expected to be partnered ahead of the pivotal Phase III registration trial programme. OI is a rare disease that is better known as brittle bone disease, where different genotypes are characterized by varying degrees of skeletal fragility. The hallmark of OI is that bone fractures happen with only minimal to moderate trauma. ASTEROID, a 112 adult OI patient Phase IIb clinical trial performed across 27 specialist sites in the US, Europe and Canada, formed the basis of discussions with the EMA and FDA.

A suitable partner, and an attractive deal, are the next steps

The outline of a single international Phase IIb/III trial, involving c 165 children aged two to 18 with OI (Type I, III, and IV) and using fracture rate at 12 months as the primary endpoint, has been agreed with regulators to support a potential approval. The plan is to partner setrusumab ahead of the formalisation of the final trial design. Management is exploring a number of options but, given its strong relationships with the OI patient communities and KOL (key opinion leaders), is keen to retain commercial rights in certain regions. In September 2020, the FDA granted setrusumab Rare Pediatric Disease Designation, which could result in a grant of a priority review voucher from the FDA. This could be redeemed to obtain priority review for any subsequent MAA/BLA or be sold or transferred to another company.

COVID-19 delayed alvelestat AATD study but provides treatment opening

Alvelestat, for α1-antitrypsin deficiency (AATD), is the second rare disease product and another suitable candidate for the retention of certain geographic rights. A proof-of-concept Phase II trial (ASTRAEUS) in c 165 severe AATD patients is underway, with top-line results expected in H221. These results will form the basis of discussions with the FDA and EMA and guide the design of the pivotal Phase III trial. Interestingly, the acute lung injury that is often seen in COVID-19 infection may be ameliorated by alvelestat and a 15 patient Phase Ib/II trial (COSTA) has recently initiated in hospitalised adults with moderate to severe COVID-19 respiratory disease. Two additional investigator sponsored studies are underway: a Phase I/II in bronchiolitis obliterans syndrome (BOS) after allogeneic hematopoietic stem cell transplant, and a Phase II (ATALANTa) in AATD.

Partnering process is underway, with two minor assets left

The three remaining clinical programmes have commercial merit but are not well suited for marketing by a specialist oncology, or rare disease focused sales team and are either already partnered or being prepared for partnering:

- Navicixizumab, the second oncology asset, was licensed to OncXerna in January 2020. It is an anti-DLL4/VEGF bispecific monoclonal antibody that targets and inhibits both Delta-like ligand 4 (DLL4) in the Notch stem cell signalling pathway and vascular endothelial growth factor (VEGF). The dual mechanism offers the potential of anti-angiogenic, anti-cancer stem cell, and immune-modulatory effects. It has FDA Fast Track designation for the treatment of patients with high-grade ovarian, primary peritoneal or fallopian tube cancer who have received at least three prior therapies and/or prior bevacizumab. Deal terms included a $4m upfront, and an additional $2m payment conditional on a CMC (chemistry, manufacturing, and controls) milestone. Up to $302m in future clinical, regulatory, and commercial milestones could be achieved; with tiered royalties (mid-single-digit to sub-teen) on global annual net sales; and a negotiated percentage of sub-licensing revenue from certain sub-licensees.
- Acumapimod is a small molecule orally active inhibitor of p38 MAP (mitogen-activated protein) kinase that is in development for acute exacerbations in COPD (AECOPD). A 282-patient Phase IIb study (AETHER) with two different dosing regimens (high and low dose) showed a statistically significant improvement in primary endpoints, with a significant reduction in severe exacerbations also seen in the follow-up phase of the study. Management is seeking separate funding to develop acumapimod further.
- Leflutrozole is an aromatase inhibitor being explored as a once-weekly oral treatment to improve infertility associated with hypogonadotropic hypogonadism (HH) in obese men. Results from the 24-week Phase IIb study showed normalisation of testosterone levels in over 75% of patients at all dose levels, with over 90% of patients normalising at the two higher levels (the lower dose was trending towards, but failed to achieve, statistical significance). All three doses saw significant improvement in FSH and LH levels. Total sperm motility and levels of fatigue also improved. The six month extension study corroborated these results. Discussions with potential global licencing partners are progressing.

Plenty of near- and medium-term news flow

In terms of news flow, the near-term value inflection points centre around greater detail on the etigilimab's development plans, notably the format of the forthcoming Phase Ib/II study, and the successful closing of a setrusumab partnering deal which will enable its Phase III programme to start. Management has stated its intention to detail the plans for the etigilimab trial, and provide more information on its positioning, through a webcast in Q420.

Valuation

Our rNPV valuation gives a value of 101p/share or $5.06/ADS (fully diluted)

We value Mereo BioPharma using an rNPV model of the clinical pipeline, which is then netted out against the cost of running the business and net cash. We have updated our model post-H120 reporting, and it now yields a valuation of £570m or $741m, equivalent to 101p/share or $5.06/ADS (fully diluted).

Exhibit 2 summarises the contributions of each clinical programme, with additional detail regarding our expectations available in our September 2020 Outlook.

Exhibit 2: Mereo BioPharma rNPV-based valuation

	Total NPV ($m)	Total NPV (£m)	Likelihood of approval	rNPV ($m)	rNPV (£m)	rNPV/ ADS ($)	rNPV/ share (p)	Notes
Setrusumab (BPS-804)	860.3	661.7	60%	451.2	347.1	5.12	102.5	Peak sales: $915m (£704m) Launch year: 2024
Alvelestat (MPH-966)	416.4	320.3	25%	93.7	72.0	1.06	21.3	Peak sales: $375m (£288m) Launch year: 2025
Egitilimab	388.4	298.7	30%	100.2	77.1	1.14	22.8	Peak sales: $1bn (£769m) Launch year: 2025
Navicixizumab	43.0	33.1	25%	43.0	33.1	0.49	9.8	Peak sales: $739m (£568m) Launch year: 2025
Acumapimod (*BCT-197)	156.5	120.4	60%	36.7	28.2	0.42	8.3	Peak sales: $640m (£492m) Launch year: 2025
Leflutrozole (*BGS-649)	140.2	107.8	50%	18.4	14.1	0.21	4.2	Peak sales: $452m (£348m) Launch year: 2025
Operating costs	(16.8)	(12.9)		(16.8)	(12.9)	(0.19)	(3.8)	
Net cash	14.9	11.4		14.9	11.4	0.17	3.4	At FY20e
Total	**2,002.8**	**1,540.6**		**741.2**	**570.2**	**8.42**	**168.3**	
Total (fully diluted)						**5.06**	**101.1**	Based on all options, warrants, bonus shares and convertible debt
Discount rate							12.5%	
Exchange rate ($/£)							1.30	
Taxation							10.0%	From 2026 with the benefit of UK Patent Box

Source: Trinity Delta; Note: *The rNPV of acumapimod and leflutrozole includes a deal success factor of 40% and 30%, respectively.

Financials

H120 shows slowdown in R&D spend, which is set to rise in H220 as TIGIT trial begins

Mereo BioPharma posted a H120 operating loss of £16.7m (H119: £18.8m), mainly due to the £3.4m drop in R&D costs to £8.5m (H119: £11.9m). This decrease was largely owing to timing, with the completion of the Phase IIb setrusumab study and pause in patient recruitment in the alvelestat trial. R&D spend is expected to rise once the etigilimab Phase Ib/II study programme starts in Q420. G&A rose by £1.3m to £8.2m (H119: £6.9m), mainly reflecting a one-off £0.9m increase in legal and professional fees to £2.4m.

Cash resources of £56.8m in place, runway now extends to early 2022

The company ended H120 with cash resources of £56.8m (FY19: £16.3m) and total debt of £27.8m (FY19: £20.5m). Net cash outflows from operating activities were £11.2m (H119: £27.6m). The £1.7m net cash inflow from investing reflected the navicixizumab out-licensing, while net cash inflows from financing activities of £49.6m resulted from the convertible loan notes, securities purchase agreements, and private placement.

The $70m equity raise has transformed the balance sheet

In February 2020, Mereo BioPharma strengthened its balance sheet through three transactions totalling £11.8m, which was followed in June by a $70m (£56m gross) private placement. A detailed breakdown of the financing transactions is presented in the September 2020 Outlook. We note that the H120 accounts included a one-off, non-cash, financing charge of £94.7m in connection with the private placement. This represented the change in fair value of the embedded derivative and warrants between the deal announcement and the passing of shareholder resolutions at the June 2020 General Meeting.

No single investor owns more than 9.9% of voting rights

Following the General Meeting, £21.7m of the June 2020 Convertible Loan Notes (CLNs) automatically converted into 125.1m new ordinary shares. As no new ordinary shares will be issued which would result in any investor holding more than 9.9% of voting rights in Mereo BioPharma as a result of the relevant conversion, an aggregate principal amount of £18.87m of CLNs remain outstanding and are held on the balance sheet.

Forecasts show funding through to early-2022

The additional funds raised during H120, coupled to prior cash resources, and anticipated R&D tax credit receipts (R&D tax credits for FY19 are expected to be received in Q420) should fund the company's currently committed clinical trials, operating expenses, and capex into early-2022. In early October, Mereo BioPharma filed a $200m shelf registration and an $50m at-the-money facility, which in our view provides the company with additional flexibility.

Updated forecasts are detailed overleaf

Following the H120 results, we have updated our forecasts. The key P&L changes in FY20e concern the non-recurring financing charge and accounting treatment of the navicixizumab out-licencing to OncXerna. We had previously recognised the $4m upfront payment as revenue; however, the transaction has been recognised as a 'loss on disposal' of £11.3m (net) in the H120 accounts. We treat both these items as exceptionals. In addition, we continue not to include in our estimates any potential upfront payment that may be associated with a near-term setrusumab deal. Our financial summary is presented in Exhibit 3.

Exhibit 3: Summary of financials

Year-end: Dec 31	£'000s	2017	2018	2019	2020E	2021E
INCOME STATEMENT						
Revenues		**0**	**0**	**0**	**0**	**0**
Cost of goods sold		0	0	0	0	0
Gross Profit		**0**	**0**	**0**	**0**	**0**
R&D expenses		(34,607)	(22,703)	(23,608)	(20,450)	(18,196)
G&A expenses		(7,045)	(9,585)	(14,273)	(14,590)	(8,830)
Underlying operating profit		**(41,652)**	**(32,288)**	**(37,881)**	**(35,039)**	**(27,026)**
Share-based payments		(3,652)	(2,190)	(1,636)	(2,060)	(2,101)
Other revenue/expenses		0	0	1,035	0	0
EBITDA		**(45,268)**	**(34,439)**	**(36,905)**	**(34,903)**	**(27,113)**
Operating Profit		**(45,304)**	**(34,478)**	**(38,482)**	**(37,099)**	**(29,127)**
Financing costs/income		(1,647)	(2,828)	(2,636)	(4,274)	(1,192)
Exceptionals		0	0	0	(105,953)	0
Profit Before Taxes		**(46,951)**	**(37,306)**	**(41,118)**	**(147,326)**	**(30,319)**
Adj. PBT		**(43,299)**	**(35,116)**	**(40,517)**	**(39,313)**	**(28,218)**
Current tax income		8,152	5,277	6,274	3,876	3,639
Net Income		**(38,799)**	**(32,029)**	**(34,844)**	**(143,450)**	**(26,680)**
EPS (p)		**(56.2)**	**(44.8)**	**(39.0)**	**(110.6)**	**(7.9)**
Adj. EPS		**(51.9)**	**(42.2)**	**(38.4)**	**(21.3)**	**(7.3)**
DPS (p)		**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)		69.0	71.4	89.4	338.7	338.7
BALANCE SHEET						
Current assets		**63,177**	**34,495**	**30,435**	**42,102**	**18,434**
Cash and cash equivalents		50,045	25,042	16,347	34,769	11,889
Short-term investments		2,500	2,500	0	0	0
Accounts receivable		509	609	572	2,203	1,652
Inventories		0	0	0	0	0
Other current assets		10,123	6,344	13,516	5,130	4,893
Non-current assets		**33,159**	**32,781**	**56,014**	**41,944**	**39,954**
Property, plant & equipment		153	149	11,558	10,068	8,078
Intangible assets		33,005	32,632	44,456	31,876	31,876
Current liabilities		**(9,618)**	**(16,177)**	**(29,878)**	**(16,082)**	**(15,002)**
Short-term debt		(1,940)	(6,838)	(15,139)	(10,602)	(9,369)
Accounts payable		(3,024)	(4,570)	(6,352)	(2,394)	(2,547)
Other current liabilities		(4,654)	(4,769)	(8,387)	(3,086)	(3,086)
Non-current liabilities		**(24,234)**	**(18,328)**	**(16,315)**	**(61,404)**	**(61,404)**
Long-term debt		(18,813)	(14,647)	(5,373)	(12,738)	(12,738)
Other non-current liabilities		(5,422)	(3,681)	(10,942)	(48,666)	(48,666)
Equity		**62,483**	**32,771**	**40,256**	**6,560**	**(18,019)**
CASH FLOW STATEMENTS						
Operating cash flow		**(31,423)**	**(23,139)**	**(45,931)**	**(28,769)**	**(21,624)**
Profit before tax		(46,951)	(37,306)	(41,118)	(147,326)	(30,319)
Non-cash adjustments		6,451	3,609	1,784	115,707	5,307
Change in working capital		3,021	2,406	(7,666)	(7,883)	704
Interest paid		724	0	0	(817)	(1,192)
Taxes paid		5,331	8,152	1,069	11,551	3,876
Investing cash flow		**(4,796)**	**252**	**43,295**	**1,687**	**(23)**
CAPEX on tangible assets		(2,296)	(34)	(21)	(22)	(23)
Acquisitions/disposals		0	0	10,074	1,670	0
Other investing cash flows		(2,500)	286	33,242	39	0
Financing cash flow		**34,070**	**(2,075)**	**(5,710)**	**45,134**	**(1,233)**
Proceeds from equity		15,000	(42)	(1,759)	18,829	0
Increase in loans		20,000	(2,111)	(1,739)	29,533	(1,233)
Other financing cash flow		(930)	78	(2,212)	(3,229)	0
Net increase in cash		**(2,149)**	**(24,962)**	**(8,346)**	**18,052**	**(22,880)**
Exchange rate effects		(1,384)	(41)	(349)	370	0
Cash at start of year		53,578	50,045	25,042	16,347	34,769
Cash at end of year		**50,045**	**25,042**	**16,347**	**34,769**	**11,889**
Net cash at end of year		**31,792**	**6,057**	**(4,165)**	**11,428**	**(10,219)**

Source: Company, Trinity Delta Note: FY20 exceptionals include aggregate non-cash finance charges of £94.7m (changes in fair value of the embedded derivative and warrants in connection with the June private placement), and a £11.3m net loss in disposal (navi licence agreement with OnXerna).

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Disclaimer

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