Company Note

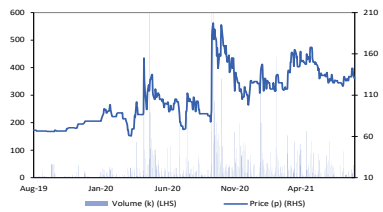
FY results

10 August 2021

Corporate

Current price	**135p**
Sector	**Healthcare Equipment and Services**
Code	**FAB.L**
Listing	**AIM**

Share Performance



	1m	3m	12m
FAB.L	+4.1%	-13.3%	+21.0%

Source: Refinitiv, Allenby Capital

Share Data		
Market Cap (£m)		**34.9**
Shares in issue (m)		**25.9**
52 weeks (p)	High	Low
	197p	**77p**
Financial year end		**31 March**

Source: Company Data, Allenby Capital

Key Shareholders	
Invest Northern Ireland	12.4%
Amati Global Investors	9.1%
Viridian Growth Fund	7.0%
Octopus Investments	5.9%
Hargreave Hale	5.4%

Source: Company Data, Allenby Capital

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Fusion Antibodies plc (FAB.L)

Steady growth with leading new service in prospect

Fusion showed solid FY21 revenue growth of 7% to £4.2m (vs £3.9m), particularly as client projects were delayed by the COVID-19 pandemic. Operating loss rose marginally from £1.1m to £1.2m (reported net profit in FY21 was distorted by a £1.7m non-cash, accounting charge). This reflects strong R&D investment in the new OptiMAL service; this is due to gain commercial revenues in FY23. Fusion should then experience narrowing losses on the trajectory to profitability. After a £3m gross capital raise in FY21, year-end cash was £2.7m (up from £1.5m). A milestone of £150k was received in July (FY22), illustrating the potential of the portfolio of future revenues as completed projects move into clinical development with clients.

- **OptiMAL** (Optimized Mammalian Antibody Library) continues its development with proof-of-concept studies underway. OptiMAL is positioned as a novel, high-value service that could give a substantial increase in revenues. The next stage, in CY 2022, will be to run pilot projects with selected clients. The focussed library of human genes used in OptiMAL is much more compact than for alternative randomised approaches. However, the aim is that the resulting therapeutic antibodies should spare clients months of further optimisation work before moving to production. The key benefit appears to be to reduce the pre-clinical risk. The technology is potentially protected by a patent application that could run, if granted, till 2039.

- **Forecast of steady growth.** We continue to expect steady revenue growth of about 10% pa, as the established RAMP service, which optimises candidate monoclonal antibodies from current high-throughput, random bacterial section systems, continues to gain clients. Fusion has a particular reputation with its clients for rescuing projects that have generated poor, unstable antibodies with low production yields. Fusion is also expert in ”hot” therapeutic areas like complex bispecifics and CAR T-cell design.

- **Cost control and cash conservation**. Fusion aims to keep cost growth at about 5% pa whilst OptiMAL development completes. Cash raised of £2.8m net in April 2020 should be sufficient to reach full commercialisation.

- **Valuation**: Fusion is currently valued at an EV to sales of about 7.5 indicating its strong specialist science base and strong long-term growth prospects. Cash as of 31 March was £2.7m. The first additional milestone, worth £150,000, was received in July 2021 as the original client licensed a project. Fusion has a broadening set of rights to further payments as various projects progress into clinical development.

Year End: March					
(£'000)	**2019**	**2020**	**2021**	**2022E**	**2023E**
REVENUE	2,182	3,895	4,165	4,582	5,040
ADJ. EBITDA	-1,077	-437	-535	-1,094	-20
ADJ. PBT	-1,500	1,073	-1,264	-1,547	-384
ADJ. EPS (p)	-5.7	-3.2	-11.3	-5.4	-1.3
NET CASH (£m)	1.98	1.38	2.52	1.15	0.42
EV/REVENUE (x)	15.3	8.5	7.4	7.0	6.5
EV/EBITDA (x)	N/A	N/A	N/A	N/A	N/A

Allenby Capital acts as Nomad & Broker to Fusion Antibodies.

Specialist services in optimising monoclonal design

Fusion works as a specialist contract research company in therapeutic antibody development, design and optimisation. This is a competitive space with several companies offering services and also performed by internal pharmaceutical research groups. Fusion offers a package of higher-value, bespoke services to save clients months of development work and, by raising manufacturing yields, improve their profitability.

Antibodies – key to immune defence and therapeutic attack

When we are immunised, for example against the COVID-19 virus, SARS-CoV-2, our antibody producing cells shuffle and mutate a set of antibody genes, test (mature) them against the target and produce multiple different antibodies: a polyclonal response. However, one immune cell clone can only make one antibody, a monoclonal - but it and its daughter cells can make a lot of it.

Monoclonals as therapeutic agents are some of the bestselling and most expensive therapies and hard for competitors to replicate as production is complex. Biotech companies mass produce monoclonal antibodies in huge bioreactors for therapeutic use. The manufacturing yield is important for the price as this remains an expensive production method since only mammalian cells are used to manufacture therapeutic antibodies.

A massive market started in mice

The original method for discovering new therapeutic monoclonals uses mouse hybridomas, invented in the 1970s. However, the hybridoma route remains cumbersome and often yields monoclonal antibodies that cause immune reactions. Fusion does still use this method and it is reliable as a first stage in developing a therapeutic antibody. But this is not the major element of Fusion's business. It is also possible to examine the antibodies made by patients, after for example a viral infection, to develop a therapeutic antibody in a process called B-Cell Cloning. This gives a more direct way to design a new therapeutic.

But …. humans aren't mice

The next advance was humanisation, dating from the 1980s. This was developed as the early mouse-based products had big side effects. The humanisation technique involves modifying the antibody genes from the cell clone. It leads to monoclonals that do not cause an immune reaction when injected into patients and have excellent therapeutic properties. This process remains a hand-built, craft specialty. Fusion has a large part of its business in this area and has a good reputation. Fusion is developing the use of machine learning (also called Artificial Intelligence (AI)) to optimise the changes to the antibody structure that need to be made. This, branded Antibody Workbench by Fusion. should speed up the time needed and potentially give better products.

Finding therapeutic gold in a haystack of bacteria

Next up was the idea of using Phage (bacterial viruses) to randomly find new antibodies; this dates from the early 1990's. The innovation was using fragments of human antibody genes and producing multiple variations in bacteria using bacterial viruses: phages. This gives huge numbers of possible antibodies: a thousand billion different forms. These are then screened using automated lab robots.

As useful antibodies are found, they are taken into further rounds of optimisation, known as **maturation**, so the antibodies bind more tightly to the target (and not to other proteins as this would cause side effects). Eventually, candidate therapeutic monoclonal antibodies are obtained. As this is highly automated and large scale, it suits certain contact providers. Although phage display led to the biggest selling therapeutic antibody drug ever, Humira from AbbVie to treat rheumatoid arthritis and other autoimmune disorders, Fusion notes that relatively few products have been made using phage. This is because raw candidate antibody gene sequences in bacteria may not transfer easily to the much more complicated mammalian cells used for production. There can be major issues around low

yield and instability. The manufacturing process (in mammalian cells) adds complex sugar structures to the finished antibodies. This helps stability but may give problems in patients. Services in phage display are a commodity market so Fusion offers higher-value maturation services.

Fusion ramps up its rational offering

Fusion specialises at the end of the discovery process with its Rational Affinity Maturation Platform (RAMP) now becoming a major revenue stream. By contrast, other common approaches use random mutation. Fusion takes un-optimized antibodies, for example arising from a phage-design process, and optimises them in mammalian cells to get the best affinity and yields. Within the market, Fusion has a reputation for rescuing phage-designed candidates that have poor gene sequences, might be unstable (not acceptable in e therapeutic), and that have low production yields.

The Fusion approach can also be applied to other antibody types, for example, those derived from camelids (like Llama) cells. Camelid antibodies, sometimes called Nanobodies, are compact with simpler structures than human antibodies and have useful properties due to their size. The first therapy based on these was approved in 2019.

The next leap, optimise directly in mammalian cells

The next big technology step for Fusion is OptiMAL – that is Optimized Mammalian Antibody Library. This gets back to the concept of working with stable, non-immunogenic human antibodies from the outset.

The Fusion approach performs the screening and maturation of a focussed, high-quality human antibody gene library in mammalian cells. This automatically means that the antibodies are compatible with standard cell production systems. The antibody structures are inherently more stable. And, as the genes are human in origin, the antibodies have much a lower risk of immune reactions in patients.

The library of genes used is smaller than for random phage display, but the outputs should be much more useful and save clients months of further optimisation work before moving to production. The key benefit appears to be to reduce the pre-clinical risk. The technology is potentially protected by a patent WO2020084298A1, currently in application phase, that could run till 2039.

Commercialization of OptiMAL

Currently, OptiMAL is not an active client service. Fusion is running proof of concept studies to validate the approach and complete development. The service could be launched in 2022 with some pilot client projects. As a premium service, this could become the major revenue generator for Fusion.

Hot science and advanced therapy development

There are other active areas of therapeutic development that have arisen from bio-engineering antibodies. The newer techniques use artificial proteins based on antibodies to target immune cells, for example, to enable them to find and kill cancer. These are:

- bispecific antibodies (also called BiTEs); and
- Chimeric Antibody Receptors (CAR) that are used to target lethal hunter-killer immune cells (CD8+ T-cells) to cancer cells. One CAR T-cell can kill a thousand cancer cells with exquisite specificity.

Bispecific boom

Bispecifics are a big new trend; in cancer they are also bispecific T cell engagers (BiTEs). They combine a specific antibody binding region to target another protein, usually a

cancer specific antigen on a cancer cell, with a receptor (CD30) that activates killer T-cells. By linking killer T-cells to cancer cells, the activated T-cells destroy the cancer. There are now three approved products, an approved example is Blinctyto (Blinatumomab, Amgen) and over 100 others in development.

Fusion can help with the binding optimisation process in the product design stage. It can also help with complex manufacturing optimisation – this in not trivial since bispecific products require up to four genes to be inserted into the production cell line and combined correctly to make active products whilst a normal antibody drug needs two which naturally associate. This makes manufacturing at high yield much more complex. Bispecific also have many other uses apart from cancer, for example, in diagnostic testing.

CAR T-cells – receptor optimisation the key the therapeutic success

CAR T-cells are very sophisticated, ultra-expensive cellular custom-made therapies for individual cancer patients with very specific blood cancers. Eventually, they may become off-the shelf standardised products against a range of cancers - but not yet. There are three approved products, but all target the same blood cell protein (CD19). Fusion can again help the design of such products as each CAR requires an optimised antibody-based binding protein. Because these are cell-based, the binding needs to be tuned differently to normal antibody drugs. This creates further design challenges.

COVID-19 potential therapy

Fusion is part of the Northern Ireland Coronavirus Antibody Development Alliance (NICADA), looking for new therapies against COVID-19. This is a publicly funded project involving Queen's University. The project is evaluating routes to new therapeutic candidates to neutralise the virus. It has no immediate commercial impact on Fusion but could be an interesting longer-term generator of significant value.

Commercial deals with long-term potential

Fusion normally offers its sophisticated services on a fee for service basis using fixed contracts. If possible, it will seek some share of any eventual client profits though milestones and a small royalty; the first payment for this has been received. This potential revenue stream could be lucrative but success in development is not guaranteed, and any additional payments are likely to be some years away. Academic customers are usually pure fee for service; Fusion has several prestige academic customers in the US.

As of 31 March 2021, Fusion had 15 such client agreements. Of these, nine could deliver royalties if the products reach the market; timing is not known as development is the responsibility the clients. There are six agreements which could deliver up to £1.5m in further milestones. Again, timing and probabilities are not predictable and these are not in our forecast or valuation. Of the milestones, £150,000 was received in July 2021.

Financials

Fusion's FY21 results show revenue of £4.2m (+7%) with operating loss marginally higher at £1.2m. Reported net profit in FY21 was distorted by a £1.7m non-cash adjustment included in the tax change, to reflect the de-recognition of a previously recognised deferred tax asset. Fusion still retains tax loss carry-forwards of c£9m that may be applied to future profits; it is just the accounting treatment of them that has changed.

The company is based in Belfast as a former spin out from Queen's University. It has a staff of 55 people, the majority of which are scientists.

Exhibit 1: Summary financials

Year-end: March 31 (£000s)

INCOME STATEMENT	**2019**	**2020**	**2021**	**2022E**	**2023E**
Revenues	2,182	3,895	4,165	4,582	5,040
Cost of goods sold	-1,378	-2,123	-2,141	-2,268	-2,570
Gross Profit	804	1,772	2,024	2,314	2,469
Other income	86	56	194	70	20
G&A Expenses	-2,061	-2,413	-2,835	-3,067	-2,593
Underlying operating profit	-1,411	-976	-1,230	-1,523	-359
Share based payments	-98	-83	-19	-19	-19
Acquisition related amortisation	0	0	0	0	0
Exceptionals	0	0	0	0	0
Other revenue/expenses	0	0	0	0	0
EBITDA	-1,077	-437	-535	-1,094	-20
Adjusted EBITDA	-1,077	-437	-535	-1,094	-20
Operating Profit	-1,508	-1,059	-1,249	-1,543	-379
Interest income	9	-14	-15	-3	-6
Exceptionals	0	0	0	0	0
Profit Before Taxes	-1,500	-1,073	-1,264	-1,547	-384
Current tax income	235	376	-1,635	151	46
Net Income	-1,264	-697	-2,899	-1,396	-339
EPS (p)	-5.7	-3.2	-11.3	-5.4	-1.3
Average no. of shares	22.1	22.1	25.6	25.7	25.9
Gross margin	*37%*	*45.5%*	*48.6%*	*50.5%*	*49.0%*

BALANCE SHEET	**2019**	**2020**	**2021**	**2022E**	**2023E**
Current assets	3,306	2,802	4,705	3,417	2,904
Cash and cash equivalents	1,984	1,537	2,686	1,314	584
Accounts receivable	1,056	887	1,440	1,506	1,657
Inventories	243	340	480	497	563
Other current assets	23	38	99	100	100
Non-current assets	2,937	3,238	1,125	900	721
Property, plant & equipment	1,588	1,470	1,123	898	719
Intangible assets	6	4	2	2	2
Other non-current assets	1,342	1,764	0	0	0
Current liabilities	-796	-989	-996	-1,131	-1,033
Short-term debt	0	-161	-163	-163	-163
Accounts payable & accruals	-462	-415	-344	-504	-426
Accruals/deferred revenues	-242	-318	-373	-373	-373
Tax payables	-25	-73	-71	-71	-71
Non-current liabilities	-93	-239	-87	-87	-87
Other non-current liabilities	-93	-239	-87	-87	-87
Equity	5,354	4,812	4,747	3,099	2,504

CASH FLOW STATEMENTS	**2019**	**2020**	**2021**	**2022E**	**2023E**
Operating cash flow	-1,098	-160	-1,136	-1,147	-549
Net income	-1,264	-697	-2,899	-1,396	-339
Non-cash adjustments	520	719	748	468	378
Change in working capital	-126	171	-688	77	-295
Interest paid/(received)	0	0	0	3	6
Taxes paid/(received)	-229	-353	1,703	-300	-300
Investing cash flow	-1,381	-103	-362	-225	-180
CAPEX on tangible assets	-1,381	-109	-365	-225	-180
Financing cash flow	-28	-184	2,647	0	0
Proceeds from equity	0	0	2,815	0	0
Repayment of borrowings	-36	-172	-182	0	0
Other financing cash flow	9	-12	14		0
Net increase in cash	-2,507	-447	1,149	-1,372	-729
Cash at start of year	4,625	1,984	1,537	2,686	1,314
Cash at end of year	1,984	1,537	2,686	1,314	584
Net cash at end of year	1,984	1,376	2,523	1,151	421

Source: Company; Allenby Capital

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