Trinity Delta

# Allergy Therapeutics

Update

## FY21 results show continued strong growth

23 September 2021

**Allergy Therapeutics has reported solid FY21 trading, with revenues up 8% (6% CER) to £84.3m (FY20: £78.2m). Pre-R&D operating profit rose 19% to £16.9m (FY20: £14.2m) given lower promotional and marketing spend due to COVID-19 restrictions, coupled with tight cost control. R&D investment increased from £9.0m to £12.9m to support the two key programmes: the G309 Grass MATA MPL exploratory field study and the VLP Peanut *ex vivo* biomarker study. Cash of £40.3m (FY20: £37.0m) is sufficient to fund the two Grass MATA MPL Phase III trials and the VLP Peanut Phase I trial. These two development programmes could transform the company's medium-term prospects, underpinning entry into the commercially important US market. Our updated valuation is £350.7m, or 54.7p per share.**

| Year-end: June 30 | 2020 | 2021 | 2022E | 2023E |
|---|---|---|---|---|
| Revenues (£m) | 78.2 | 84.3 | 86.1 | 89.2 |
| Adj. PBT (£m) | 3.5 | 2.5 | (12.9) | (17.4) |
| Net Income (£m) | 6.9 | 2.9 | (12.9) | (18.1) |
| Adj.EPS (p) | 1.1 | 0.5 | (2.0) | (2.8) |
| Cash (£m) | 37.0 | 40.3 | 22.9 | 16.2 |
| EBITDA (£m) | 12.2 | 8.2 | (7.7) | (11.9) |

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

- **Resilient FY21 results** FY21 revenue increased 8% (+6% CER) from £78.2m to £84.3m. Pre-R&D operating profit grew 19% to £16.9m (FY20: £14.2m), delivering a 20% margin (FY20: 18%), helped by non-R&D operating costs increasing by only £1.4m to £45.9m (FY20: £44.5m) as COVID-19 restrictions limited promotional and marketing opportunities. R&D spend rose by £3.9m to £12.9m (FY20: £9.0m) as VLP Peanut and Grass MATA MPL progressed. Net profit was £2.9m (FY20: £7.1m including the legal settlement of £3.2m). Cash stood at £40.3m (FY20: £37.0m).

- **Germany is the stand-out performer** All key markets and products performed well, with consistent share gains as the science-based marketing approach continues to gain traction. Revenue growth was driven by a solid performance in Germany (+10% CER to £52.8m), now representing 64% of group sales (FY20: 61%). Other regions faced greater COVID-19 headwinds, reflected in fewer patient visits. ImmunoBON, a novel OTC product for mild allergies, recently launched in Germany and Austria.

- **Key R&D programmes are progressing well** The VLP Peanut vaccine *ex-vivo* study successfully met all primary and secondary endpoints; confirming safety is as hoped with clear indications of a material shift from a Th2-dominated (allergic) response to a Th1-dominated (tolerant) response. This paves the way for a US Phase I trial that could start enrolment in Q122. The G309 exploratory Grass MATA MPL field study is expected to publish key data during H221. The results will guide the pivotal G306 Phase III registration trial for this commercially important opportunity.

- **Valuation of £350.7m, or 54.7p/share** The solid balance sheet funds Allergy Therapeutics key clinical assets through several value-inflection points. Near- and medium-term news flow should provide opportunities to revisit our current valuation of £350.7m (54.7p/share); of which the existing commercial business contributes £91.1m (14.2p/share) and the R&D pipeline £222.8m (34.7p/share).

| | |
|---|---|
| Price | 37.6p |
| Market Cap | £241.3m |
| Enterprise Value | £201.0m |
| Shares in issue | 641.8m |
| 12-month range | 12.4-38.5p |
| Free float | 22.4% |
| Primary exchange | AIM London |
| Other exchanges | N/A |
| Sector | Healthcare |
| Company Code | AGY |
| Corporate client | Yes |


### Company description

Allergy Therapeutics specialises in the diagnosis and treatment of allergy. The existing European business generates over £80m annual sales. Near-term R&D efforts are focussed on the Pollinex Quattro platform, whilst in the medium-term the VLP platform is highly promising.

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# Allergy Therapeutics: executing operationally

**Allergy Therapeutics has demonstrated the resilience of its European operations with another solid performance in FY21. Revenues were up 8% (+6% CER) to £84.3m (FY20: £78.2m). This was driven by strong growth in Germany (10% CER), which now represents 64% of group revenues (FY20: 61%). A record year-end cash balance of £40.3m (H121: £48.3m; FY20: £37.0m), provides funding to achieve several important value inflection points. Management is executing a clear strategy: maximising the performance of its existing commercial platform; developing a suite of innovative products that address well-documented needs; and preparing for geographic expansion, notably the US. The continued strong commercial performance in Europe forms the foundation of the business and is helping to fund the development of novel R&D programmes that represent major growth opportunities. Updating our model following FY21 results generates a new Allergy Therapeutics valuation of £350.7m (54.7p per share) vs £344.5m, or 53.8p, previously.**

**Commercial operations continue to deliver consistent growth**

Allergy Therapeutics' European allergy business has delivered another solid set of results. The resilient performance, despite COVID-19 headwinds, means the 23-year record of 9% underlying growth is maintained. The quality of these commercial revenue streams is an important element of our investment case; however, it is the two key R&D programmes, the Grass MATA MPL short-course allergy treatment and VLP Peanut allergy vaccine, that could transform the company's medium-term outlook.

**Results due in H221, will guide EU and US registration trial**

The next catalyst for Allergy Therapeutics is expected to be top-line results from the c 150 patient multi-centre G309 exploratory Grass MATA MPL Phase III field study before end-2021. These results will guide the design of the G306 pivotal grass trial which will support European and FDA filings and potential US approval. In Europe, this will enable wider prescribing, not restricted to a 'named patient' basis as is currently the case. In the US, Grass MATA MPL will likely become the first approved commercially available short-course, subcutaneous, aluminium-free grass allergy immunotherapy. G306 is scheduled to start in autumn 2022, over the 2022/23 allergy season, with an autumn 2023 read out.

**Novel VLP peanut vaccine could be a game changer for patients**

The second highlighted programme, VLP Peanut allergy, addresses a sizeable and underserved market and is the first Virus Like Particle-based vaccine in Allergy Therapeutics' portfolio. The *ex vivo* biomarker study (P001) undertaken in collaboration with Imperial College London produced highly encouraging results, with VLP Peanut achieving all primary and secondary endpoints. Importantly, the study confirming the hypoallergic nature of the vaccine candidate and the potency of the immune response induced. Results were discussed at a recent Key Opinion Leader event, and detailed in our September 2021 Update. These data, together with additional preclinical studies, will support an IND filing with the FDA; a Phase I study (PROTECT) is planned to start in early calendar 2022.

## Continued growth and market share gains

**Market share gains highlight strength of scientific messaging**

The FY21 results highlight the quality of Allergy Therapeutics' business with growth maintained across all its key allergy products, despite the challenging

market conditions due to COVID-19 restrictions, with consistent market share gains. The performance continued that seen at H121, with revenues up by 8% (+6% CER) to £84.3m (FY20 £78.2m), with growth across all key products supported by the science-based marketing approach. As in H121, performance varied geographically, largely influenced by COVID-19 impacts. Growth was again stronger in Northern Europe (notably Germany) where allergy clinics are largely standalone vs a weaker performance in Southern Europe where hospital-based allergy clinics were impacted as resources were diverted elsewhere.

**Pollinex Quattro remains one of the key growth contrubutors**

The Pollinex Quattro (grass allergy), Pollinex (grass allergy targeted to traditional prescribers), Acarovac (perennial mite allergy) and Venomil (wasp and bee stings) vaccines were key growth drivers. Pollinex Quattro, first introduced in 1999, is Allergy Therapeutics' largest product. It has transformed the SCIT (subcutaneous immunotherapy) landscape by providing high immunogenicity and low reactogenicity through only four injections. It is currently only available In Europe on a "named patient" basis but is set to become more widely prescribed once the clinical trial programme leads to regulatory approval and enables promotion to the wider physician audience.

**Regulatory environment plays to Allergy Therapeutics' strategy**

The market share gains reflect management's strategy to exploit the greater regulatory oversight that is underway across Europe, driven by Germany's Therapieallergene-Verordnung (TAV), through a focus on producing strong supporting scientific data. The Grass MATA MPL development programmes are an apt example, with the trials currently underway set to demonstrate the clinical benefits of Pollinex Quattro (PQ) ultra-short courses.

## Novel "farm effect" ImmunoBON launched

**A novel approach to capture OTC mild allergy business…**

Allergy Therapeutics' commitment to developing and commercialising innovative allergy and immunology products is also evident with ImmunoBON, a protein-based oral product that mimics the "farm effect", aiming to replicate the reduced allergic reactions seen in people who live on or close to livestock farms. It is an over-the-counter product with a dose of two lozenges a day for adults and one a day for children older than three, with a minimum treatment period of three months. It was recently launched in Germany and Austria, with a positive consumer reception, and its positioning and marketing messages will be refined and replicated across other European markets.

**….with a scientifically supported marketing campaign**

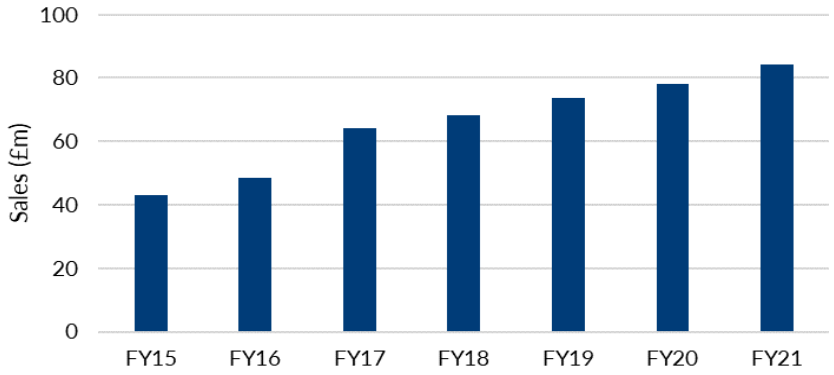
ImmunoBON is targeting a new market segment for Allergy Therapeutics: mild allergy. However, despite initial targeting for mild allergic rhinitis, data suggests a positive role for more problematic allergies, including birch and house dust mite. Further development work is underway exploring use against grass, cat, dog, and horse allergies. ImmunoBON is based on whey protein from organic raw milk (providing β-Lactoglobulin and various lipocalins) with iron, zinc & vitamin A added to boost the immune response.

# Financials

**Strong German performance is the stand-out contributor**

Allergy Therapeutics FY21 results (12 months ending 30 June 2021) showed revenues up 8% (+6% CER) to £84.3m (FY20: £78.2m), with growth nearly in line with the 9% CAGR seen over the past 23 years. Geographic variations in sales growth were largely influenced by COVID-19 impacts on hospital-based allergy patient visits and diversion of resources to COVID-19 related areas. Germany posted growth of 10% CER to £52.8m (FY20: £48.0m), now representing 64% of group revenues (FY20: 61%). Ex-Germany sales were flat (CER) at £30.5m (FY20: £30.2m), with Spain up 4%, Netherlands up 3%, and Austria up 7%.

**Exhibit 1: Allergy Therapeutics revenue growth since 2015**




Source: Trinity Delta, Allergy Therapeutics

**Pre-R&D operating profit up strongly (+19%) as COVID curtails marketing activities**

Cost of goods increased to £22.1m (FY20: £20.2m) reflecting additional Brexit costs. However, coupled with resilient sales performance, this translated into increased gross profit of £62.2m (FY20: £58.0m), with gross margin stable at 74%. Operating profit pre-R&D was £16.9m, up 19% (FY20: £14.2m), with a pre-R&D operating margin of 20% (FY20: 18%). Sales, marketing, and distribution costs of £25.2m (FY20: £24.9m) reflected the continued reduction in science conference attendance and promotional activity due to COVID-19. Other administrative expenses grew by £1.1m to £20.7m (FY20: £19.6m) due to spend on compliance, IT, pharmacovigilance, and additional logistics costs.

**R&D set to rise as development programmes progress**

R&D investment rose by £3.9m to £12.9m (FY20: £9.0m excluding the £3.2m exceptional received from the Inflamax litigation settlement). This largely reflects the progress of the Grass MATA MPL Phase III programme, with the fully recruited exploratory G309 study on track to deliver results before end-2021, and the VLP Peanut Imperial College *ex vivo* study now complete. R&D expenditure is expected to continue to rise once the pivotal Grass MATA MPL G306 Phase III trial and the VLP Peanut Phase I PROTECT trial start in 2022. Investment is also being directed into other pre-IND work for the VLP Peanut allergy programme, the safety database for Grass MATA MPL, preparatory work for a planned Birch MATA MPL pivotal field trial (B302), early-stage work on two new VLP programmes (melanoma and asthma), and the ongoing TAV processes.

**Solid balance sheet underpins company through to key inflection points**

Cash and equivalents were strong at £40.3m (H121: £48.3m; FY20: £37.0m). Management expects that current resources will be sufficient to fund the forthcoming G306 Grass MATA MPL trial as well as the Peanut Phase I PROTECT trial, with a small amount of additional debt. An overdraft facility of £7m was recently renewed but remains unused. The funding needs of the business are

constantly reviewed and, given the plans for geographic expansion into the important US market, a path to a dual AIM and NASDAQ listing is being explored.

**FY22 and FY23 forecasts see further revenue growth, but also increased R&D investment as programmes progress**

For FY22 we expect full-year sales of £86.1m, pre-R&D operating profit of £5.6m, and R&D investment of £17.0m. Non-R&D operating costs should rise broadly in line with sales resulting in a reported operating loss of £11.4m and net loss of £12.9m. We also introduce our forecasts for FY23. Here we expect sales of £89.2m, pre-R&D operating profit of £6.1m, and R&D costs of £22.1m as both the G306 and PROTECT trials will be ongoing. Non-R&D operating costs should rise broadly in line with sales resulting in a reported operating loss of £16.0m and net loss of £18.1m. Our forecasts are presented in Exhibit 2.

**Valuation updated to reflect FY21 performance…**

Applying our new forecasts to our valuation model generates an updated Allergy Therapeutics valuation of £350.7m (equivalent to 54.7p per share), with the commercial base business contributing £91.1m (14.2p/share) and the pipeline an additional £222.8m (34.7p/share). This compares with a prior £344.5m (53.8p) valuation: with an £89.7m (14p) value for the commercial business contributing and £210.3m (32.8p) for the R&D pipeline.

**…but still employing conservative assumptions**

We value the company using a sum of the parts model which includes a DCF for the base business (comprising detailed expectations of the European cash flows over a five-year forecast period) and a pipeline rNPV model of the main developmental stage allergy immunotherapy programmes. In line with our philosophy, we use conservative assumptions throughout and have previously detailed our valuation methodology in our September 2020 Initiation.

## Exhibit 2: Summary of financials

| Year-end: June 30 | £'000s | 2019 | 2020 | 2021 | 2022E | 2023E |
|---|---|---|---|---|---|---|
| **INCOME STATEMENT** | | | | | | |
| **Revenues** | | **73,717** | **78,204** | **84,331** | **86,088** | **89,220** |
| Cost of goods sold | | (18,379) | (20,201) | (22,106) | (24,105) | (22,305) |
| **Gross Profit** | | **55,338** | **58,003** | **62,225** | **61,984** | **66,915** |
| R&D expenses | | (12,987) | (9,000) | (12,887) | (17,011) | (22,114) |
| S&M expenses | | (26,995) | (24,853) | (25,200) | (30,492) | (34,151) |
| G&A expenses | | (17,595) | (19,627) | (20,674) | (26,473) | (27,273) |
| **Underlying operating profit** | | **(2,239)** | **4,523** | **3,464** | **(11,993)** | **(16,623)** |
| Share-based payments | | (1,367) | (794) | (635) | (648) | (661) |
| Exceptionals | | 6,037 | 3,152 | 0 | 0 | 0 |
| Other revenue/expenses | | 593 | 634 | 567 | 578 | 590 |
| **EBITDA** | | **6,481** | **12,223** | **8,163** | **(7,654)** | **(11,928)** |
| **Operating Profit** | | **4,391** | **8,309** | **4,031** | **(11,414)** | **(16,033)** |
| **Operating profit (pre R&D)** | | **11,341** | **14,157** | **16,918** | **5,597** | **6,081** |
| Financing costs/income | | (98) | (238) | (374) | (225) | (152) |
| **Profit Before Taxes** | | **4,293** | **8,071** | **3,657** | **(11,639)** | **(16,185)** |
| **Adj. PBT** | | **(3,704)** | **3,491** | **2,455** | **(12,865)** | **(17,435)** |
| Current tax income | | (826) | (1,159) | (771) | (1,276) | (1,880) |
| **Net Income** | | **3,467** | **6,912** | **2,886** | **(12,915)** | **(18,065)** |
| | | | | | | |
| **EPS (p)** | | **0.5** | **1.1** | **0.5** | **(2.0)** | **(2.8)** |
| **Adj. EPS** | | **(0.5)** | **0.5** | **0.3** | **(2.2)** | **(3.0)** |
| **DPS (p)** | | **0.0** | **0.0** | **0.0** | **0.0** | **0.0** |
| Average no. of shares (m) | | 632.8 | 635.2 | 639.2 | 641.8 | 641.8 |
| | | | | | | |
| *Gross margin* | | *75%* | *74%* | *74%* | *72%* | *75%* |
| *EBITDA margin* | | *9%* | *16%* | *10%* | *N/A* | *N/A* |
| *Underlying operating margin* | | *N/A* | *6%* | *4%* | *N/A* | *N/A* |
| | | | | | | |
| **BALANCE SHEET** | | | | | | |
| **Current assets** | | **46,625** | **55,170** | **57,858** | **45,841** | **35,088** |
| Cash and cash equivalents | | 27,440 | 36,962 | 40,273 | 22,933 | 16,231 |
| Short-term investments | | 0 | 0 | 0 | 0 | 0 |
| Accounts receivable | | 9,776 | 8,076 | 6,222 | 7,194 | 7,333 |
| Inventories | | 9,409 | 10,132 | 10,838 | 15,189 | 11,000 |
| Other current assets | | 0 | 0 | 525 | 525 | 525 |
| **Non-current assets** | | **21,872** | **31,055** | **30,231** | **31,254** | **32,157** |
| Property, plant & equipment | | 11,481 | 20,417 | 19,717 | 20,454 | 21,071 |
| Intangible assets | | 4,840 | 4,736 | 4,754 | 4,740 | 4,726 |
| Other non-current assets | | 5,551 | 5,902 | 5,760 | 6,060 | 6,360 |
| **Current liabilities** | | **(16,859)** | **(18,227)** | **(18,230)** | **(20,271)** | **(28,292)** |
| Short-term debt | | (694) | (829) | (963) | (813) | (813) |
| Accounts payable | | (15,736) | (15,148) | (16,475) | (17,861) | (25,431) |
| Other current liabilities | | (429) | (2,250) | (792) | (1,597) | (2,048) |
| **Non-current liabilities** | | **(14,080)** | **(24,215)** | **(21,324)** | **(20,557)** | **(20,090)** |
| Long-term debt | | (1,742) | (2,927) | (2,450) | (2,150) | (2,150) |
| Other non-current liabilities | | (12,338) | (21,288) | (18,874) | (18,407) | (17,940) |
| **Equity** | | **37,558** | **43,783** | **48,535** | **36,267** | **18,863** |
| | | | | | | |
| **CASH FLOW STATEMENTS** | | | | | | |
| **Operating cash flow** | | **5,600** | **12,010** | **8,341** | **(11,639)** | **(1,228)** |
| Profit before tax | | 4,293 | 8,071 | 3,657 | (11,639) | (16,185) |
| Non-cash adjustments | | 3,531 | 4,736 | 3,281 | 4,633 | 4,917 |
| Change in working capital | | (2,245) | 589 | 1,552 | (3,637) | 11,920 |
| Interest paid | | (204) | (489) | (190) | (225) | (152) |
| Taxes paid | | 225 | (897) | 41 | (771) | (1,729) |
| **Investing cash flow** | | **(3,353)** | **(2,509)** | **(2,639)** | **(4,801)** | **(5,025)** |
| CAPEX | | (3,099) | (2,547) | (2,562) | (4,484) | (4,708) |
| Acquisitions/disposals | | 0 | 0 | 0 | 0 | 0 |
| Other investing cash flows | | (254) | 38 | (77) | (317) | (317) |
| **Financing cash flow** | | **9,545** | **(110)** | **(2,034)** | **(900)** | **(450)** |
| Proceeds from equity | | 10,196 | 1 | 4 | 0 | 0 |
| Increase in loans | | (651) | 1,232 | (132) | (450) | 0 |
| Other financing cash flow | | 0 | (1,343) | (1,906) | (450) | (450) |
| **Net increase in cash** | | **11,792** | **9,391** | **3,668** | **(17,340)** | **(6,703)** |
| Exchange rate effects | | 115 | 131 | (357) | 0 | 0 |
| Cash at start of year | | 15,533 | 27,440 | 36,962 | 40,273 | 22,933 |
| **Cash at end of year** | | **27,440** | **36,962** | **40,273** | **22,933** | **16,231** |
| **Net cash at end of year** | | **25,004** | **33,206** | **36,860** | **19,970** | **13,268** |

Source: Company, Trinity Delta

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